

FACT SHEET

Sixth Report to the Leaders on the U.S.-Japan Regulatory Reform and Competition Policy Initiative

June 6, 2007

OVERVIEW

Established in 2001, the U.S.-Japan Regulatory Reform and Competition Policy Initiative (Regulatory Reform Initiative) aims to enhance economic growth by creating new business opportunities, strengthening competition, and improving the overall business environment. As a key component of the U.S.-Japan Economic Partnership for Growth, both Governments exchange annual recommendations under the Initiative and, following working and high-level discussions, prepare this annual Report to the Leaders to outline progress.

This year's Report, the sixth under this Initiative, documents important measures taken by Japan in key sectors such as telecommunications, information technology, intellectual property rights, medical devices and pharmaceuticals, financial services, agriculture, competition policy, transparency, legal reform, commercial law, and distribution. Among other areas, progress reflected in this Report will help to lower barriers to business, enhance transparency, streamline import procedures, and speed regulatory decisions.

It remains important for Japan to strengthen its move toward regulatory reform in the coming months and years, as these measures have benefited consumers and businesses while spurring economic growth. This Sixth Report to the Leaders also highlights several areas where Japan is actively pursuing or considering further reform that should also fulfill these important objectives.

Sixth Report to the Leaders

PROGRESS HIGHLIGHTS

TELECOMMUNICATIONS

- Introducing mobile number portability which permits consumers to choose mobile operators more easily and thus furthers competition.
- Initiating a change of rules that will permit less burdensome certification requirements for wireless local area network equipment (e.g. WiFi equipment).
- Clarifying the applicability of interconnection rules to resale-based mobile operators.
- Committing to begin an examination of interconnection rules applicable to NTT's "Next-Generation Network," based on the Internet protocol.
- Reforming its universal subsidy program by introducing a rational system for assessing charges on a per-number basis.

INFORMATION TECHNOLOGIES

- Enacting legislation in May 2007 to prohibit recording of movies in movie theaters while extending penalty provisions under Japan's Copyright Law to those who commit such acts.
- Launching new initiatives with the U.S. Government to combat trade in counterfeit and pirated goods through intensified bilateral, regional, and multilateral action in Asia and the world.
- Implementing reforms designed to increase competition and transparency in bidding processes for government procurements of information technology (IT) systems.
- Concluding studies in FY2007 on whether to adopt measures that would extend the term of protection for sound recordings, establish a pre-set statutory compensation system for infringement, and provide broader authority to investigate and prosecute copyright crimes.
- Amending the Industrial Technology Enhancement Act to allow contractors to own intellectual property rights (IPR) for software developed through government-sponsored programs, thereby increasing opportunities to commercialize this IPR.
- Ensuring a transparent review of the Personal Information Protection Act (PIPA) by holding multiple rounds of hearings with stakeholders, disclosing meeting schedules and minutes, and soliciting and publishing public comments received.
- Publishing confirmation online that non-compliance with voluntary privacy guidelines will not result in penalties to firms under Japan's PIPA.
- Creating websites in English to explain the legal implications for technology companies and Internet service providers of introducing anti-spam technologies in the context Japanese law.

- Supporting efforts to verify the interoperability of different health IT systems, publicizing the results of this verification process, and promoting the use of interoperable systems in Japan.
- Collaborating with the Federal Trade Commission to translate the *econsumer.gov* website into Japanese to enhance consumer protection and confidence in e-Commerce.

MEDICAL DEVICES AND PHARMACEUTICALS

Medical Devices/Pharmaceuticals

- Establishing goals for the Pharmaceuticals and Medical Devices Agency (PMDA) to help cut the drug lag by reducing by 2.5 years the period from drug development to approval.
- More than doubling PMDA drug reviewers by 2010 to help speed new drug approvals.
- Planning to stimulate drug clinical trials, including staff increases at 40 clinical trial facilities.
- Increasing by 30 percent the number of medical device reviewers by 2009.
- Forming a task force to improve reviews of medical device technological upgrades.
- Clarifying that the Ministry of Health, Labor and Welfare (MHLW) accepts foreign clinical data for medical devices to the greatest extent possible.
- Taking steps to stimulate development of vaccines in Japan, including publication of the “Vision” report and establishment of a committee to promote the vaccine industry.
- Planning to provide the U.S. medical device industry with opportunities to discuss with MHLW major issues such as the Foreign Average Price rule and the C1 and C2 pricing procedures.
- Creating an industry-MHLW study group on pricing rules for in-vitro diagnostics.
- Providing opportunities for U.S. industry to discuss with MHLW reform of Japan’s drug pricing system, frequency of price revisions, and the re-pricing criteria for market expansion.
- Initiating twice-yearly meetings between MHLW and the blood products industry.
- Facilitating exchanges of information between industry and MHLW on advertising for drugs, including over-the-counter products.

Nutritional Supplements/Cosmetics/Quasi-drugs

- Eliminating a form for the import of nutritional supplements and a more than doubling of the number of quarantine stations offering consultations to companies before import.
- Confirming that the presence of naturally occurring food additives in a shipment of nutritional supplements is not, by itself, a violation of the Food Sanitation Law.
- Starting a dialogue with industry on regulations for cosmetics and quasi-drugs, including on advertising and labeling claims for cosmetics and lead times for approval of quasi-drugs.

FINANCIAL SERVICES

- Studying new ways to increase Tokyo's competitiveness as an international financial center and including domestic and foreign financial institutions and industry associations in subsequent deliberations.
- Preparing to implement the Financial Instruments and Exchange Law, which updates Japan's capital markets-related laws, and through outreach and public comment requests soliciting input of stakeholders as draft rules are finalized.
- Expanding use of credit information and mandatory use of lenders' exchanges by consumer finance firms.
- Reviewing the corporate pension system, including outreach to the private sector for input on improving the defined contribution pension system.

COMPETITION POLICY

- Strengthening deterrence against Antimonopoly Act (AMA) violations, including filing criminal accusations in two cases, ordering a record 36.3 billion yen (\$300 million) in surcharges against 165 companies in FY2006, and maximizing the effectiveness of JFTC's leniency program.
- Improving the fairness of JFTC procedures, including by ensuring that a majority of its hearing examiners are not career JFTC employees, setting out factors relating to stays of enforcement orders, and promising to respond to a request for its current enforcement intentions with respect to stock acquisitions.
- Taking steps to address the conflicts of interest that can arise from the current *amakudari* system, including submitting legislation in April 2007 to restrict the reemployment of retiring government officials and requesting that companies receiving public works orders not place former Ministry of Land, Infrastructure and Transport (MLIT) officials in their sales offices.
- Formulating MLIT measures to prevent bid rigging, including extending the period of suspension from bidding and suspension of construction licenses and expanding the coverage of open bidding procedures by FY2008 to cover 90 percent of all contracts let by MLIT by value.
- Increasing measures to uncover bid rigging by requiring each central government agency, public corporation, and local government entity covered by a 2006 Cabinet Decision to implement an administrative leniency program to complement the JFTC leniency program.
- Strengthening competitive bidding at the local government level by requesting local governments to expand the general open bidding system, install electronic bidding systems, and promote publication of bid contract-related information.

TRANSPARENCY

- Ensuring information about all government-appointed advisory groups is made accessible through the portal e-Gov website, thus enhancing the transparency of Japan's advisory committees' activities.
- Addressing concerns from the public regarding the application of Japan's new public comment procedure rules by Ministries and Agencies and, as necessary, promoting better implementation.
- Cooperating with the United States to promote high transparency standards in the Asia-Pacific.

- Publishing the effective date of new regulations well in advance of their entry into force.
- Continuing transparent administration of Special Zones, including the national application of measures.
- Finishing approximately 80 English translations of key Japanese laws and regulations as of April 2007 and adding 50 new translations to the total number of translations planned.

OTHER TRADE-RELATED GOVERNMENT PRACTICES

- Adopting pest quarantine restrictions on imported lettuce based on international standards.
- Engaging in technical work with the United States on Japan's enforcement policy on maximum residue limits, consistent with international obligations to apply SPS measures only to the extent necessary to protect human life or health.
- Reviewing before December 2007, and if necessary revising, a 10 million yen cap placed on third sector insurance products sold by smaller financial institutions to certain borrower companies.

PRIVATIZATION (JAPAN POST)

- Affirming that Japan Post Bank and Japan Post Insurance must meet the same obligations and standards including risk management and compliance systems to those of private financial institutions when they sell new or altered financial products.
- Ensuring the Financial Services Agency (FSA) has sole authority over the supervision and inspection of Japan Post Bank and Japan Post Insurance under the Banking Law and Insurance Business Law.
- Confirming that FSA will apply the same standards to Japan Post Bank and Japan Post Insurance as those applied to other banks and insurance companies, including when engaging in sales and distribution of financial services or insurance products.
- Supervising through FSA the Japan Post Network, including its employees, when acting as an agent or intermediary to order any financial transactions.
- Ensuring that the Japan Post Network's relationships with the new postal financial companies are undertaken in a fair manner, consistent with the arms-length rule and other applicable rules and regulations.
- Taking measures to eliminate perceptions of an "implicit government guarantee" for postal deposits and insurance products sold from October 1, 2007.
- Moving to apply the 'duty declaration' system, in principle, to international postal items valued over 200,000 yen.
- Enhancing the transparency of the Japan Post privatization process, including with respect to the Japan Post Implementation Plan, by taking steps to provide stakeholders opportunities to express views.
- Recognizing the importance of transparency of the Postal Services Privatization Committee and continuing to implement ex-ante and ex-post transparency measures related to the Committee's operation.

COMMERCIAL LAW AND LEGAL SYSTEMS REFORM

- Implementing in May 2007 new legal provisions permitting triangular mergers using foreign shares and permitting tax deferral when certain conditions are met; monitoring whether tax deferral conditions allow investors to take advantage of the new rules to make revisions if necessary.
- Supporting efforts by the stock exchanges to facilitate active proxy voting, with the Tokyo Stock Exchange (TSE) making efforts to encourage listed companies to provide proxy materials to shareholders three to four weeks before the shareholders meeting.
- Publicizing the Ministry of Health, Labor and Welfare's view that there is a fiduciary duty on pension fund managers to exercise proxy voting rights solely in the interest of beneficiaries.
- Implementing in December 2006 amendments to the Tender Offer System that require the board of directors of a company that has received a tender offer bid to publish its position on the bid and to disclose the measures it has taken to avoid potential conflicts of interests of directors in preparing that position.
- Announcing that TSE will establish codes of conduct on corporate activities by the end of 2007 and will consider adopting codes addressing the need for outside directors and ensuring their independence by narrowing the definition of who qualifies as an outside director.
- Adopting TSE, Osaka Stock Exchange and JASDAQ rules requiring listed companies to disclose details of any anti-takeover measures and restricting the ability of listed companies to adopt anti-takeover measures that seriously harm the interests of shareholders.
- Taking steps, upon receipt by the Ministry of Justice of a request from foreign legal consultants (*gaiben*), toward legal revisions that would permit *gaiben* to form professional corporations and to establish multiple offices.
- Examining seriously the legal implications of allowing Japanese lawyers to be members of international legal partnerships.
- Confirming that *gaiben* may, on a case-by-case basis, act as neutrals in alternative dispute resolution (ADR) procedures that do not fall within their scope of authority.
- Ensuring that the Public Comment Procedure will be used when adopting or revising laws, ordinances and guidelines related to implementation of the Act on Promoting the Use of ADR.

DISTRIBUTION

- Beginning to introduce the new one-stop omnibus vehicle registration mechanism, which will help streamline procedures for operators of fleet vehicles.
- Considering improvement in enforcement of parking regulations and procedures, including for distribution vehicles, that includes input from U.S. and other industry.
- Committing to review the impact of new city planning regulations after in effect to ensure they do not restore the prior adjustment system for large-scale stores or restrict the large-scale store business model.