

FACT SHEET

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

July 6, 2009

OVERVIEW

The U.S.-Japan Regulatory Reform and Competition Policy Initiative (Regulatory Reform Initiative) is a vehicle to encourage greater economic growth through steps to open up new business opportunities, improve the overall business environment, and strengthen competition in the marketplace. Through this Initiative, United States had continued to strongly urge Japan to pursue an ambitious agenda of economic and regulatory reform that meet these important goals.

Following an exchange of detailed recommendations in October of 2008, both Governments engaged in work under the auspices of four working groups as well as in the Initiative's High Level Officials Meeting process. Progress achieved through this work is in turn outlined in the 2009 Report to the Leaders.

The following are highlights of steps that Japan has taken or will take that respond to U.S. Government recommendations under this Initiative and that are included in the 2009 Report to the Leaders.

PROGRESS HIGHLIGHTS

COMMUNICATIONS

- Enacting a framework for licensing 3.9G mobile services, opening new market opportunities for U.S. device and service suppliers.
- Initiating a process for developing recommendations to promote competition in the mobile sector, including consideration of payment-free interconnection ("bill-and-keep").
- Designating the next-generation networks of the NTT East and NTT West as Category I Designated Telecommunications facilities, helping to ensure cost-oriented and non-discriminatory interconnection with competing carriers.
- Identifying possible new technical requirements for mobile multimedia broadcasting that would allow multiple technologies and providers to be considered for future licenses for mobile multimedia broadcasting services.

INFORMATION TECHNOLOGIES

- Strengthening protections for music and motion pictures by amending the Copyright Law to make illegal Internet downloads knowingly made from unauthorized sources.
- Creating new opportunities for certain electronic fund transfer providers by introducing the legal framework necessary to offer such services in Japan.
- Completing reviews by ministries and agencies of their privacy guidelines to ensure consistency with standardized Cabinet Office guidelines, thereby improving predictability for companies to comply with privacy requirements.
- Launching an improved database of government information systems procurements to provide more transparency for all IT vendors and potential bidders, including by posting procurement plans, specification documents and tender notice information.
- Ensuring opportunities for input by U.S. right holders in policy deliberations affecting limitations and exceptions to copyright protections in Japan.
- Committing to further strengthening of bilateral cooperation to boost intellectual property protections, including through work in the Asia Pacific Economic Cooperation forum and through an Anti-Counterfeiting Trade Agreement.
- Establishing reimbursements for remote diagnostic imaging technologies used in telemedicine, creating new opportunities for medical equipment suppliers.
- Launching a 3-year Personal Health Record Project to facilitate the collection and storage of lifetime personal health information in a manner compliant with international standards.

MEDICAL DEVICES AND PHARMACEUTICALS

- Reducing waiting times for drug clinical trial consultations by reforming the system to allow the Pharmaceutical and Medical Devices Agency to respond to all consultations in a timely manner.
- Implementing a program to accelerate the review of medical devices that includes hiring more review staff, measuring reviewer performance, publishing review times for device approvals, and providing U.S. industry with meaningful opportunities to discuss the progress of the program.
- Committing to improve drug review times by increasing the number of drug reviewers and improving the quality and consistency of review.
- Providing the pharmaceutical and medical device industries meaningful opportunities to provide input on critical reimbursement issues prior to final policy decisions.
- Establishing a system to document instructions given at pre-shipment consultations to improve the consistency of guidance from quarantine stations during the import process for nutritional supplements.

- Publishing a list of active ingredients from previously approved medicated cosmetics applications to increase transparency in the approval process.
- Improving the accessibility of regulatory information on cosmetics and quasi-drugs and working with industry to provide key documents in English.

FINANCIAL SERVICES

- Passing legislation that opens the market for the introduction of non-bank e-payment services.

COMPETITION POLICY

- Strengthening deterrence against hard-core cartels and bid rigging by amending the law to increase penalties against cartel ringleaders and lengthen maximum prison sentences, thereby extending the statute of limitations for administration and criminal enforcement actions.
- Committing to review and reform the Japan Fair Trade Commission's (JFTC's) administrative hearing procedure within Japan FY2009.
- Improving the effectiveness of JFTC's "leniency" program to encourage reporting of illegal acts by allowing companies in the same corporate group to jointly file leniency applications, and increasing to 14 the number of Japanese institutions that have adopted a complementary Administrative Leniency program.
- Seeking public input on draft guidelines to clarify the types of monopoly conduct that, pursuant to new Antimonopoly Act amendments, will be subject to administrative fines.

COMMERCIAL LAW AND LEGAL SYSTEMS REFORM

- Considering new steps that improve the investment environment, including by strengthening Tokyo Stock Exchange (TSE) rules to better protect shareholder interests prior to the introduction of corporate takeover defensive measures and with regard to third party allocations.
- Examining new steps to improve shareholder rights through new TSE rules that would make annual shareholders' meeting notices and all proxy materials more accessible.
- Issuing a Financial Systems Council Study Group recommendation that stronger disclosure requirements on cross-shareholding arrangements be implemented.
- Seeking a conclusion within 2009 on necessary measures to permit foreign lawyers, among themselves or with Japanese lawyers, to establish professional corporations that can establish multiple offices.
- Considering new measures that would ensure that the content of a trade secret will not be disclosed in criminal prosecutions for theft of such trade secret.

TRANSPARENCY AND OTHER TRADE-RELATED GOVERNMENT PRACTICES

- Finalizing a new import inspection framework for maximum residue levels (MRLs) that includes steps that facilitate trade in U.S. horticultural products.
- Approving new food additives already considered safe around the world, thereby opening new opportunities for exports of U.S. food products.
- Increasing the number of public comment periods that are longer than 30 days and actively encouraging and promoting the better implementation of the public comment procedure.
- Submitted legislation to streamline re-entry procedures for foreign nationals residing in Japan, and clarified requirements for obtaining domestic employee visas in a manner that expands the scope of eligibility.
- Producing approximately 260 official English translations of Japan's laws and regulations as of the end of April 2009, improving access to information for companies operating in Japan.
- Committing to a transparent process for future reviews to renew the Policyholder Protection Corporation (PPC) system to protect policyholders, including by providing opportunities for input by all interested parties.

PRIVATIZATION (JAPAN POST)

- Leveling the playing field in customs treatment for high-value items sent via international postal express service compared to requirements imposed on international express carriers for similar services.
- Launching an expert-level review on the scope of Japan's international postal express service, including in light of its simplified requirements for customs treatment (compared to those required of private international express carriers).
- Requiring Japan Post Service to carry out its international physical distribution business in a manner that ensures fair competition with private carriers.
- Providing opportunities for input by interested parties in the 2009 Postal Services Privatization Commission's triennial review of the Japan Post privatization process.