

# UNITED STATES-JAPAN ECONOMIC HARMONIZATION INITIATIVE

FEBRUARY 2011

The Government of the United States welcomes the opportunity, through this new U.S.-Japan Economic Harmonization Initiative, to support growth in our respective economies by taking steps that create new opportunities, facilitate new business and trade, and enhance the public welfare. The Government of the United States also looks forward to working closely together with Japan toward harmonization, to the extent feasible, of our respective systems, regulatory approaches, and other measures and policies in ways that promote this shared goal.

Building on cooperation with Japan is an area of particular focus for the United States under this Initiative. Positive results have already come from U.S.-Japan cooperation in areas such as information and communication technologies, intellectual property rights, agriculture-related measures, and vaccines. Through this Initiative, the United States will continue to promote greater harmonization and coordination with Japan in these and potentially other areas in pursuit of our shared goals.

## U.S. AGENDA ITEMS

### INFORMATION AND COMMUNICATION TECHNOLOGIES

#### Communications

Spectrum: Foster greater competition and innovation by taking steps to improve objectivity, transparency, and accountability in Japan's spectrum assignment process, including authorization of the use of auctions.

Dominant Carrier Regulations: Promote competition and consumer choice by ensuring that any reforms related to NTT or its affiliates adequately address means to safeguard competitive opportunities, in particular for new market entrants, and that the policymaking process is conducted in an open, unbiased manner without undue influence from NTT. Submit any recommendations for reforming the structure of the NTT Group to a public notice and comment process.

Mobile Interconnection Rates: Ensure fair pricing practices that benefit consumers through initiating a study to determine whether mobile termination rates are set at levels that reflect the principle of cost-orientation under efficient management, consistent with Japanese law.

Converged and Internet-enabled Services: As regulations are updated or developed regarding converged and Internet-enabled services, ensure that Japan's regulatory approach allows for innovative products and services, such as Internet-delivered video, and that dominant players do not distort competition in the market.

Transparency: Ensure and foster fair market opportunities and consumer choice for emerging technologies by taking steps to improve the transparency and accountability of the Ministry of Internal Affairs and Communications' (MIC) policymaking process, including study and advisory groups, in light of MIC's regulatory and policymaking roles.

International Cooperation: Continue to seek opportunities to cooperate on Information and Communication Technologies (ICT) issues of common concern, including at the World Trade Organization, such as by developing common principles on key issue areas.

### ***Information Technologies***

Government ICT Procurement: Introduce greater competition, transparency, and fairness in government procurement of ICT through steps such as implementation of national government-wide policies that reflect international technology trends and standards and that follow principles of technology neutrality and interoperability.

Health Information Technology (HIT): Improve the quality and efficiency of healthcare for Japanese patients by rapidly implementing HIT that is based on international standards, that promotes technology neutrality and interoperability, and that allows patients greater access to their own health records.

Cloud Computing: Facilitate the free flow of data across borders in order to maximize cloud computing technology's potential to strengthen growth and innovation throughout society. Adopt the principle of non-discrimination between data services offered inside and outside Japan. Work transparently and consult foreign and domestic industry as rules on data centers and cloud computing are made and implemented.

Privacy: Introduce greater uniformity in the enforcement of the Privacy Act across all central government entities through policy standardization and consistent implementation of guidelines. Adopt a balanced approach to the protection of data by reexamining both the provisions and the application of the current privacy law to foster the appropriate sharing of data. Work transparently and consult foreign and domestic industry as guidelines are developed for the use of private data in online advertising.

## INTELLECTUAL PROPERTY RIGHTS

Technological Protection Measures: Enhance the ability of right holders to protect their works by ensuring robust protection for technological protection measures (and the business models that employ them) by providing a more comprehensive set of prohibitions and accompanying remedies for both access and copy controls, including, as appropriate, the availability of sufficient civil and criminal remedies for unauthorized acts of circumvention and trafficking in devices/services used primarily to circumvent technological protection measures.

Copyright Term Extension: Improve protection for copyright holders by extending the term for copyright protection to all works in addition to audio-visual works, in line with emerging global trends, including those of its OECD counterparts and major trading partners.

Online Piracy: Take steps to update laws and regulations and other measures to enhance enforcement against online infringement. In addition, encourage cooperative efforts among stakeholders, including Internet service providers and rights holders, to address online piracy.

Enforcement Tools: Strengthen enforcement against infringement of intellectual property rights by providing law enforcement officials, customs officials, and public prosecutors with *ex officio* authority to investigate and prosecute alleged criminal infringements on their own initiative without the need for a right holder complaint, and by adopting a system of pre-established statutory damages for copyright and trademark infringement cases as an effective remedy for rights holders.

Exceptions to Protection: Clarify that the private use exception in Japan's Copyright Law does not apply to downloads from an illegal source for all works. Also, ensure full transparency and meaningful opportunities for stakeholder input as the Japanese Government and its advisory bodies consider proposals regarding limitations or exceptions to copyright protection.

Patent Laws and Procedures: Streamline patent procedures through promotion of work share efficiencies. Review measures to promote an environment for greater innovation, such as those related to universities and small and medium-sized enterprises.

Transparency: Ensure full transparency and meaningful opportunities for stakeholder input as the Japanese Government develops and updates policies and initiatives affecting the application of copyright, including in the digital environment, and other intellectual property rights issues.

U.S.-Japan Cooperation: Promote further cooperation between the United States and Japan to ensure adequate and effective protection and enforcement of intellectual property rights domestically and worldwide.

## JAPAN POST

Level Playing Field for Insurance and Banking: To promote more consumer choice through vibrant competition in the market, establish equivalent conditions of competition for insurance and banking services, consistent with Japan's WTO obligations, by fully eliminating competitive advantages for Japan Post and ensuring equal regulatory treatment and enforcement of all suppliers.

Japan Post Reforms: Ensure full transparency and provide meaningful opportunities for input to interested stakeholders as the Japanese Government and affiliated advisory groups develop and implement changes to measures related to Japan Post that affect the conditions for competition. As Japan considers potential reforms, address long-standing level playing field concerns and avoid giving Japan Post additional competitive advantages.

Scope of Operations for Japan Post Financial Companies: Ensure that equivalent conditions of competition between Japan Post and private financial companies are established before allowing Japan Post Insurance and Japan Post Bank to expand the scope of their business operations.

Level Playing Field for International Express Delivery Services: Promote efficient competition and equivalent conditions of competition in the international express delivery sector, including by subjecting Japan Post Service to customs clearance procedures and costs for competitive services similar to those of other international express delivery service suppliers and by taking steps to prevent the subsidization of Japan Post Services' international express service (EMS) by revenue from monopoly postal services.

## INSURANCE

Insurance Cooperatives (*Kyosai*): To promote a sound and transparent regulatory environment, ensure equivalent conditions of competition between *kyosai* and private sector competitors, including equal regulatory treatment and enforcement.

Bank Sales of Insurance: To promote greater consumer choice and convenience while ensuring robust consumer protection, conduct a fact-based and transparent review of the bank sales channel in a timely manner and make any necessary changes, with

meaningful opportunities for input from interested stakeholders and taking into account global best practices.

Life Insurance Policyholder Protection Corporation (LIPPC): Ensure that a more efficient, sustainable safety net system is created before the current system expires in 2012. Ensure that full transparency is maintained as the Japanese Government considers revisions to the system.

Domestication of Foreign Insurance Operations: Ensure that foreign-incorporated insurance companies operating branches in Japan that wish to transfer business operations to a Japan-incorporated entity can do so in a seamless manner that protects policyholders and creditors while ensuring business continuity.

Independent Agents: Consider new measures to increase the competitiveness of third-party distribution channels for insurance products.

## TRANSPARENCY

Public Comment Procedure (PCP): Develop a strong, meaningful public comment system that is recognized as open and responsive to changing conditions and concerns from interested parties, including interested foreign parties, through steps to strengthen Japan's PCP by, for example, instituting longer comment periods and taking additional steps to ensure stakeholder views are fully considered before final decisions are made.

Advisory Councils and Groups: Improve the transparency and inclusiveness of government-appointed councils and similar groups when new policies and regulations are considered that may affect stakeholders and the public by introducing stronger requirements related to the formation and operation of these groups as well as their openness to stakeholders and the public.

Interpretations of Regulations: Improve transparency, predictability, and promote regulatory compliance by requiring government authorities to make public generally applicable interpretations of regulations.

## TRANSPORTATION, DISTRIBUTION AND ENERGY

Technical Guidelines for Advanced Automobile Safety Features: Enable U.S. automobile manufacturers to offer vehicles with innovative and advanced safety features to Japanese consumers in a more timely and burden-free manner by enhancing transparency in the preparation of related voluntary guidelines and by ensuring imports of such automobiles are not unduly inhibited by voluntary guidelines.

Regulatory Regime for Renewable Energy: Promote greater adoption of renewable energy technologies through streamlining and unifying related regulatory regimes, including for the approval of wind power projects.

Selection of Customs Office for Declaration: Facilitate smooth, efficient customs processing by allowing customs brokers using Nippon Automated Cargo and Port Consolidated System (NACCS) to declare express items at any convenient Customs Office.

Co-location of Customs Officials: Improve efficiency of the customs clearance process by allowing co-location of customs officials at the bonded premises of private companies, thereby eliminating travel time to customs offices for documentation checks that reduces wait times for officials to arrive to conduct physical inspections.

De Minimis: Enable a smoother flow of goods and help reduce workloads for Customs officials by at least doubling the Customs Law *de minimis* limit from the current level of 10,000 yen.

## **AGRICULTURE-RELATED ISSUES**

Pesticide Residues and Uses: Facilitate greater use of new, safer agricultural chemicals and enhance cooperation between U.S. and Japanese authorities by addressing several outstanding pesticide-related issues, including Japan's pesticide maximum residue level (MRL) review process, the framework for post-harvest use of pesticides, and enforcement policy for MRL violations. Discussion should include reference to relevant international standards and practices.

Organic Crops: Work together to apply science-based standards to assess the environmental safety of production substances used on organic crops, modify the current pesticide residue policy with the goal of enhancing organic trade, and address the labeling of organic products in both markets.

Food Additives: Enhance cooperation between U.S. and Japanese authorities and facilitate trade by completing the review of 46 food additives that are recognized as safe by Joint FAO/WHO Evaluation Committee on Food Additives and used throughout the world. To date, the reviews of six food additives have not been completed.

Gelatin: Achieve consistency with international science-based guidelines by providing market access for gelatin.

## COMPETITION POLICY

Enforcement Effectiveness: Heighten the benefits of an effective Anti-monopoly Law (AMA) enforcement program by, for example, introducing a settlement procedure, eliminating undue antimonopoly exemptions, increasing efficiency and transparency of merger review, increasing staff with graduate level economics training, hiring outside experts in appropriate enforcement matters, and developing AMA education programs for judges.

Procedural Fairness: Increase confidence in Japan Fair Trade Commission (JFTC) enforcement decisions through improvements in procedural fairness and transparency of JFTC administrative and investigatory processes, including by reforming JFTC's administrative hearing and judicial review system, enhancing procedural protections in JFTC investigations in a manner consistent with JFTC enforcement needs, and ensuring adequate opportunities for firms to respond to allegations before JFTC issues orders.

Bid Rigging: Improve competition in government procurement and eliminate bid rigging by, among other measures, strengthening rules to eliminate procurement official conflicts of interest, improving efforts to eliminate government-assisted bid rigging and expanding administrative leniency programs for companies admitted into JFTC's leniency program.

## BUSINESS LEGAL ENVIRONMENT

Cross-Border M&A: Allow Japan to benefit from enhanced inward M&A activities by taking such measures as revising legal, regulatory and tax requirements that may be impeding inward-bound M&A activities, and strengthening protections of general shareholder interests in the adoption of anti-takeover measures.

Corporate Governance: Improve efficient business practices and management accountability to shareholders through the promotion of international best practices in corporate governance, including by strengthening the role of truly independent directors, improving effectiveness of shareholder voting mechanisms, enhancing corporate disclosures and augmenting protection of minority shareholders.

Legal Services: Expand access in Japan to international legal services by, for example, allowing foreign lawyers to form professional corporations, permitting foreign law firms to open multiple offices in Japan, allowing *bengoshi* to become equal members of international legal partnerships, and revising qualification criteria and streamlining approval procedures and reporting obligations for foreign legal consultants.

## MEDICAL DEVICES AND PHARMACEUTICALS

### Pharmaceuticals and Other Issues

New Premium Pricing: Accelerate elimination of the drug lag and boost incentives for research and development by implementing the new innovation premium on a permanent basis and removing the ceiling for the premium.

Repricing for Market Expansion: Encourage companies to introduce their most successful products in Japan by eliminating or, at minimum, amending the Repricing for Market Expansion Rule so that it does not punish such products.

Foreign Price Adjustment (FPA) Rule: Ensure fairness in Japan's implementation of pricing policies by revising the FPA Rule to ensure that products are treated equally regardless of whether the Japanese price is lower or higher than the foreign price.

14-day Limit Rule: In consideration of patient benefits and access to medicine, revise the 14-day limit on new prescriptions to the minimum necessary to ensure safety.

Drug Lag: Promote the early introduction of innovative drugs into Japan and reduce the drug lag by taking steps such as considering, as appropriate, acceptance of clinical trial data from East Asian countries, ensuring drug review goals are met and requests for consultations are responded to in a timely manner, and building on recent positive interaction with industry by developing a clear mechanism that assists the Pharmaceuticals and Medical Devices Agency and the sponsor to better plan and manage the functional resources needed to support the question and answer process.

Administrative Review Period: Speed Japanese patient access to new drugs by increasing the listing of new drugs from four times a year to monthly.

User Fees: Encourage industry's continued contribution to improving efficiencies in Japan's drug approval process by beginning discussions with industry on elements of the next user fee system, including the size of the fees and the metrics that will be used to measure progress between 2012 and 2017.

Blood Products: Expand Japanese patient access to blood products by engaging in consultations with U.S. industry on self-sufficiency, labeling, regulatory, and reimbursement matters. Allow opportunities for industry to provide input, opinions, and evidence for their positions in relevant Councils and groups.

## Vaccines

Vaccine Access: Build on measures taken in 2010 with respect to Hib, pneumococcal, and HPV vaccines by finding long term solutions that promote vaccine availability throughout Japan.

Transparency: Speed the introduction of new vaccines available to Japanese patients by developing clear criteria and timelines for identifying a recommended vaccine.

Vaccine Exchanges: Encourage the GOJ's efforts toward the development of a national vaccine plan through bilateral cooperation and exchanges.

## Medical Devices

Foreign Average Price (FAP) Rule: Promote the timely introduction and stable supply of medical devices in Japan by eliminating FAP, or if that is not possible, ensuring stability in the rules and practices used to calculate FAP.

Reimbursement for In Vitro Diagnostics (IVDs): Reward advanced and improved IVD products that enhance the efficiency of Japan's healthcare system by basing reimbursement for IVDs on clinical value.

C2 Reimbursement Process for Capital Equipment: Promote the introduction of advanced capital equipment in Japan by engaging in dialogue with industry toward developing clear criteria and guidelines for: 1) establishing which products qualify for C2 designation; and 2) determining appropriate pricing for C2 products.

Elimination of Device Lag and Gap: Speed the introduction of innovative medical technology in Japan by ensuring timely implementation of the Action Program for the Speedy Review of Medical Devices.

Reducing Regulatory Burden for Companies: Improve conditions for companies that provide innovative technologies to the Japanese market by consulting with stakeholders toward modifying requirements for Quality Management Systems and Foreign Manufacturer Accreditation that create added regulatory burden for companies.

## Cosmetics

Quasi-drugs: Enable Japanese consumers to access quasi-drug products in a timely manner and without unnecessary costs by taking measures such as implementing quasi-drug approval expedition guidelines among other measures.

Advertising and Labeling: Enable Japanese consumers to make informed choices by expanding the number of advertising claims allowed for cosmetic products.

Import of Cosmetics & Quasi-drugs: Improve and streamline the import of cosmetics and quasi-drugs by optimizing the import process.

Other Transparency and Regulatory Issues: Increase transparency in the enforcement regulations on advertisements and allow both domestic and foreign stakeholder participation in the Local Advertisement Controller Meetings.

### *Nutritional Supplements*

Regulatory Categories and Claims: Allow opportunity for greater industry input on the Japanese health food system, including ways to improve the Food with Health Claims system and proposals for the system to allow ingredient-specific health claims.

Health Food Safety Regulations: Facilitate smoother trade by clarifying the process and criteria by which a new ingredient in a nutritional supplement is classified as a drug ingredient, a food ingredient, or a food additive, and consider ways to improve the import process by looking at best practices from other industrialized nations.

Food Additives: Expand the list of allowable additives, solvents and chemical forms of nutrients for nutritional supplements, to include those commonly approved in other industrialized nations.