



## **Statement of the U.S. Chamber of Commerce and the U.S.-Japan Business Council**

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### **WRITTEN COMMENTS**

**ON: "U.S.-Japan Trade Agreements"**

**TO: Subcommittee on Trade, U.S. House of Representatives Committee on  
Ways & Means**

**BY: the U.S. Chamber of Commerce and U.S.-Japan Business Council**

**DATE: November, 2019**

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The Chamber's mission is to advance human progress through an economic,  
political and social system based on individual freedom,  
incentive, initiative, opportunity and responsibility.

The U.S. Chamber of Commerce is the world's largest business federation representing the interests of more than three million businesses of all sizes, sectors, and regions, as well as state and local chambers and industry associations. The Chamber is dedicated to promoting, protecting, and defending America's free enterprise system.

More than 96% of Chamber member companies have fewer than 100 employees, and many of the nation's largest companies are also active members. We are therefore cognizant not only of the challenges facing smaller businesses, but also those facing the business community at large.

Besides representing a cross-section of the American business community with respect to the number of employees, major classifications of American business—e.g., manufacturing, retailing, services, construction, wholesalers, and finance—are represented. The Chamber has membership in all 50 states.

The Chamber's international reach is substantial as well. In addition to 117 American Chambers of Commerce abroad, an increasing number of our members engage in the export and import of both goods and services and have ongoing investment activities. The Chamber favors strengthened international competitiveness and opposes artificial U.S. and foreign barriers to international business.

The Chamber's U.S.-Japan Business Council (USJBC) is a Washington, D.C.-based business association whose mission is to support U.S. business interests in Japan and promote stronger economic ties between the United States and Japan. USJBC member companies collectively account for a substantial share of overall U.S. economic activity with Japan, and place high priorities on doing business in Japan and helping forge the most cooperative and mutually beneficial economic relationship possible between the two countries.

The U.S. Chamber of Commerce and U.S.-Japan Business Council appreciate the opportunity to present the following comments on the U.S.-Japan Trade Agreements for consideration by the House Ways and Means Trade Subcommittee.

At the outset, we would like to stress that we welcome many of the provisions included in the U.S.-Japan Digital Trade Agreement and the useful constellation of “Stage 1” outcomes on agriculture and certain industrial goods in the broader U.S.-Japan trade negotiations. While these are positive developments, we respectfully urge the Administration to hold fast to its commitment to achieve a comprehensive, high-standard trade agreement with Japan with the broad outcomes such an agreement would reflect. We also ask that Congress works to ensure that the initial package does not impede momentum toward a broader trade accord.

Addressing the full range of U.S. trade concerns through a state-of-the-art, comprehensive trade agreement is of fundamental interest to American businesses and their workers in a wide range of sectors. It is especially important because other major economies, including the European Union (through the EU-Japan Economic Partnership Agreement); and Canada and Mexico (through the Comprehensive and Progressive Agreement for the Trans-Pacific Partnership), have recently entered into market-opening trade agreements with Japan. As a result, a broad array of industries in these countries already enjoy preferential access to and treatment in the Japanese market.

The breadth of the U.S. business community’s priorities in the U.S.-Japan trade negotiations are well known. Among the areas that should be addressed in a comprehensive trade agreement with Japan are: market access and technical barriers to trade; services (including financial, telecommunications, audiovisual, express delivery, ICT, and other professional services); intellectual property, copyrights, trademarks, and trade secrets; customs administration and trade facilitation; investment; government procurement; regulatory cooperation and good regulatory practices; transparency and procedural fairness; state-owned and controlled enterprises; anti-corruption; small and medium-sized enterprises; and competition policy.

These priorities are reflected in comments submitted to the Office of the United States Trade Representative by our organizations in November 2018 and in the negotiating objectives established by Congress in the Bipartisan Congressional Trade Priorities and Accountability Act of 2015 (known as Trade Promotion Authority). While the “Stage 1” agreements omitted most of these priorities, we remain hopeful that they will be included in “Stage 2” and believe that Congress should work to ensure that these outcomes are achieved. The United States-Mexico-Canada Agreement (USMCA) serves as a model in many respects, and we believe there is a real opportunity in the trade negotiations with Japan to create a new “gold standard” trade agreement that will help U.S. firms maintain a foothold in one of the world’s most dynamic markets and regions.

Additionally, we believe that regular engagement with the private sector directly, as well as through the Advisory Committee for Trade Policy and Negotiations (ACTPN) and relevant Industry Trade Advisory Committees (ITACs), would have led to an even stronger “Stage 1” outcome. In section 135 of the Trade Act of 1974 (1974 Trade Act, 19 U.S.C. 2155), Congress established a private-sector advisory system to ensure that U.S. trade policy and trade negotiation

objectives adequately reflect U.S. commercial and economic interests; unfortunately, during Stage 1, they were not sufficiently consulted and strong outcomes could have been achieved.

The United States and Japan have built a close strategic partnership, and our bilateral relationship demands an economic partnership that is equally exceptional. We recognize Stage 2 negotiations will be challenging and stand ready to work with both sides to secure successful outcomes that strengthen ties between two of the world's largest economies. Beyond the overarching priorities outlined earlier, the members of the U.S. Chamber and the USJBC have identified a number of issue- and sector-specific priorities that are outlined in the following submission.

### **Overarching Priorities**

- **Objectives**: Generally speaking, we recommend hewing closely to the negotiating objectives established under TPA and urge the two governments to prioritize a comprehensive agreement rather than narrowly focus on the reduction of tariffs on certain goods and services.
- **Section 232 Tariffs**: These negotiations should lead to the expeditious removal of U.S. Section 232 tariffs on imports of steel and aluminum from Japan. Similarly, these negotiations should make clear that the United States will not impose Section 232 tariffs on imports of Japanese autos or auto parts.
- **Managed Trade**: We oppose “grey area” measures, such as tariff-rate or snapback quotas, voluntary export restraints, and orderly marketing agreements that limit trade and violate the World Trade Organization (WTO) Agreement on Safeguards.
- **Currency**: Any effort to address currency manipulation in this reciprocal trade agreement must not infringe in any way on the ability of the Federal Reserve Bank or the Bank of Japan to steer the conduct of U.S. or Japanese monetary policy, respectively.
- **Level Playing Field**: Ensuring a level playing field is a key governing principle for strengthening markets and avoiding market inefficiencies and distortions. Therefore, the U.S. and Japan should avoid government-created distortions in the marketplace.
- **Intellectual Property**: Considering the very strong intellectual property (IP) rights regimes in both countries, we see these negotiations as a real opportunity to set the highest global standard for IP-led creativity and innovation. Both countries should avail themselves of the opportunity to advance a model approach to sustainable access to innovation and creativity through respect for property rights and a return of fair value for innovation.
- **Third Countries**: We welcome efforts by the U.S. and Japanese governments to strengthen cooperation to better support American and Japanese companies by establishing a level playing field in policies and practices, so as to create tangible benefits for and protect both countries' and workers from non-market oriented policies and practices by third countries.
- **Multilateral Trading System**: We also welcome efforts to strengthen the multilateral trading system and its institutions.

### **Issue- and Sector-Specific Priorities**

The following issue- and sector-specific priorities are listed alphabetically by issue area and sector, and do not reflect any level of prioritization.

## **Autos**

- Remove regulatory barriers in Japan, such as Japan's only partial acceptance of Federal Motor Vehicle Safety Standards (FMVSS). These regulatory barriers focus the resources of American companies on burdensome compliance standards and prevent American companies from fully pursuing opportunities to partner with Japan on next generation auto technologies. Japan should fully accept FMVSS to allow American-manufactured vehicles to more easily enter the Japanese market.

## **Competition**

- The agreement should establish strong rules and disciplines to ensure the private sector is not disadvantaged by state-owned enterprises (SOEs). Today's trading rules never envisioned the state as an active cross-border commercial actor in export and investment. Further, it is important that the agreement also address competition enforcement to ensure it is conducted in a manner that assures due process, is based in sound economic analysis, and is not misused as a tool for industrial policy, forced technology transfer, or undermine legitimate IP rights.
- While disciplines on SOEs are not issues of direct concern in the bilateral U.S.-Japan trade relationship, it is nevertheless important that the United States and Japan stand shoulder-to-shoulder in establishing these and other much needed due process and trading principles that we can each carry forward with other trading partners in future negotiations.

## **Cosmetics**

The cosmetic and personal care products industry is a truly global industry, dependent on open markets and transparent, consistent regulatory environments around the world. A Cosmetics Annex, such as the one incorporated in the original Trans-Pacific Partnership (TPP), should be included in any U.S.-Japan trade agreement. Further, we encourage the two governments to include the following:

- Simplify the regulatory approval process by eliminating unreasonable regulations on non-active (excipient) ingredients and introducing an online product registration/notification system that allows companies to submit notification/applications directly and links notification/application information across prefectural governments, the PMDA and Customs streamlining procedures required at custom clearance.
- Expand allowable claims to include product claims that are based on verifiable data and avoid restricting claims based on the same guidance to pharmaceutical products (prohibiting (1) data usage, (2) testimonials and (3) numerical claims regarding efficacy.)
- The process for approval of Quasi Drug (QD) products should be simplified. Specifically, the Government of Japan (Ministry of Health, Labor, and Welfare, or MHLW) should initiate a system to expedite registration for QD products that are recognized to be similar to products that are already approved and for QD products that use only raw materials that have been previously approved for use by consumers by the MHLW. Process simplification for QD will expand choices for consumers to meet a variety of demands and preferences for medicated cosmetics, just as consumers have with ordinary cosmetics.
- Product risk assessments should be science-based, particularly when evaluating chemical assessment methods and aligning product classification and labeling standards with international norms.

- Regulations should be based on risk assessments using evidence and a cost-benefit analysis. This should apply both to cosmetics as well as vitamins, minerals, and botanicals used in food supplements.
- A mutual-recognition protocol should be adopted to preclude the need to duplicate testing or approval requirements and acceptance of a manufacturer's Declaration of Conformity.
- USG negotiators should consult with U.S. companies throughout the negotiations with regard to specific ingredients that will be subject to evolving regulations.
- Allow foreign companies to obtain marketing licenses directly rather than require that companies find a licensed importer or set up a subsidiary.

## Customs

Given the dramatic rise in e-commerce and the uptick in free trade agreements that Japan has been involved with over the last few years, the U.S. should encourage Japan to implement high standard trade facilitation measures, including raising the customs *de minimis* level to be at or similar to the U.S.'s level, inclusive of duties and taxes.

- Specifically, the U.S. should encourage Japan to change Article 14, Item 18 of the Customs Tariff Act from JPY10,000 to JPY100,000, inclusive of duties and taxes. Raising the customs *de minimis* levels contributes to faster and more efficient customs procedures for express shipments, particularly for international express shipments of e-commerce, thereby alleviating the workload of the Japanese government.
- In turn, this also frees up Japan Customs to target high-risk imports, such as illegal or illicit material, because those Customs agents can refocus their resources on risk-based targeting and analysis, as opposed to the considerable administrative burdens of clearing small or low-value shipments.
- Japan should also be encouraged not to require Harmonized Tariff Schedule codes on imports entering under the new, higher customs *de minimis* levels. The new, higher customs *de minimis* amount should apply to imports from all origins, and not exclusively goods of U.S.-origin.
- Additionally, the U.S. and Japanese governments should collaborate to develop a trade facilitation program for low-value shipments, most of which are traded via e-commerce. The program should include:
  - A simplified set of procedures for clearance, taxation and return of goods under a simplified common threshold, with the aim of reducing time, cost and complexity in trade.
  - A common Standard for E-Commerce Trusted Trader Accreditation which helps manage the risk of illicit shipments and support the implementation of the abovementioned trade facilitation measures.

## Digital Trade

The U.S. and Japan are generally well-aligned on principles around the digital economy and the U.S.-Japan Digital Trade Agreement is a positive step forward in many areas. As USTR moves forward with Stage 2 negotiations, we encourage Congress to work to ensure that the Digital Trade Agreement is incorporated into the final comprehensive agreement as a chapter in a genuine, TPA-compliant Free Trade Agreement, which will help to guarantee that the

commitments are codified in both legal systems. Additionally, it is our understanding that USTR is open to updating the current text during the Stage 2 negotiations. As it does so, we would suggest that Congress urge USTR to press Japan to include more robust language promoting cybersecurity to overcome a few shortcomings of the initial U.S.-Japan Digital Agreement.

### **Direct Selling**

The agreement should explicitly recognize direct selling as a legitimate and beneficial distribution service that expands consumer choice, encourages entrepreneurship and labor market flexibility, and broadens economic opportunity. At the same time, the Government of Japan should acknowledge that up-line payments based on product sales shall not be prohibited. This distribution system was recognized in the recently completed trade agreement among the United States, Mexico and Canada (USMCA, Chapter 15, Cross Border Trade in Services, Article 15.10: Paragraph 1, footnote 7). The definition of direct selling should be identical to the language in this footnote.

### **Electronic Payments**

- A U.S.-Japan trade agreement should follow the financial services commitments in the U.S.-Mexico-Canada agreement (USMCA), providing for both market access and national treatment, to ensure a level playing field for domestic and foreign-based suppliers of electronic payment services (EPS) in both markets. Regulation should account for, and be respectful of, different business models, encouraging a diverse set of players in the payments space. This competition among players will not only result in greater consumer choice, but will also spur innovation, contributing to a more robust payments ecosystem that will allow all market participants to develop and supply a wide range of payment services with differing product features and value propositions.
- Japan should be encouraged to commit to ensuring and safeguarding an open and global payment system in which transactions are processed by global networks without any requirements for local switching or processing of transactions.
- The agreement should also apply digital trade provisions to electronic payment services suppliers. Specifically, digital trade provisions of the agreement should: a) ensure EPS suppliers are able to transfer information across borders; and b) prohibit requirements to use or locate computing facilities in a Party's territory as a condition for supplying EPS in that territory.

### **Energy & Infrastructure**

- Foster a market that chooses winners based on transparent processes. Enabling all resources to compete fairly in bilateral tender, energy market, capacity market, and balancing markets, will ensure that market rules and pricing are technology-neutral and do not privilege incumbents over newcomers.
- Market opportunities should be designed as a “pre-market” mechanism, foreseeing the integration of all resources into future wholesale markets.
- Promote international consistency in technical and safety standards to ensure the participation of leading global companies in both the U.S. and Japanese markets.

### **Express Delivery Services**

The United States should support a Delivery Services Annex to ensure U.S. and Japanese businesses have access to world-class delivery service options. The parties should also commit to fair, non-discriminatory treatment of non-postal service providers. Both the U.S. and Japan should ensure that some of the unique challenges associated with market dominant players (i.e., national postal operators) in the sector are addressed with appropriate safeguards against abuse of that position. A competitive market in which both Japan Post Co., Ltd. (JPC) and private sector express carriers compete on an equal footing to offer the best service at the lowest possible price will benefit Japanese consumers and the Japanese economy as a whole. The concept should be applied to competitive, value-added delivery services, including JPC's Express Mail Service (EMS).

- To that end, the U.S. and Japan should work together to remove EMS from the postal universal service definition, and eliminate advantageous regulations for EMS or application of discriminatory regulations to private international express carriers for establishing equivalent conditions of competition.
- For example, currently the Act on Domestic Animal Infectious Diseases Control (Article 38), and the Plant Protection Act (Article 603), both exclude international postal shipments from their requirements of first entry port approval for quarantine shipments. Instead, quarantine shipments of JPC's EMS are brought to the International Post Distribution centers and checked there, without receiving an arrival airport check first. This unfairly provides time and cost advantages for EMS, which are not provided to private sector carriers. The U.S. should work with Japan to ensure that the benefit of moving quarantine shipments without a first entry port check, is applied fairly, so that shipments can undergo the quarantine check at the private sector carrier's facility outside of the airport.
- Also, JPC and private sector carriers are treated differently when it comes to Customs Clearance. Private international express carriers must use the duty declaration system whereby the carrier needs to declare all shipments for customs clearance and calculate duties and consumption taxes by their cost. However, different procedures apply to JPC, because the duty assessment system is conducted by customs officials for EMS shipments. The U.S. should urge the Japanese government to apply the same customs clearance regulations and procedures to JPC as applied to the private sector.
  - Since Japan Post has been privatized, it should be regulated in the same manner as its private sector competitors. Currently, Ministry of Internal Affairs and Communications (MIC) regulates Japan Post Corporation's postal services, whereas private companies are regulated by various ministries, including MLIT for transportation and security, MOF for customs clearance, and MAFF for quarantine procedures. Different regulatory agencies between the postal services and other private companies have led to discrepancies in regulations and disadvantages for private companies.
- Finally, the same security requirements are currently not applied to EMS and other international postal products as are applied to private sector carriers in Japan. Most notably, JPC does not have to comply with Advance Cargo Information Submission Program. However, private express carriers handling international air cargo are currently required to submit cargo information, (including the Master Air Waybill) in advance. For example, for a long haul flight longer than five hours, cargo information should be submitted three hours before arrival. As of March 2019, Japan Customs will require airlines to submit House Air Waybill information, but this requirement will not apply to shipments handled by JPC. This

discrepancy fails to adequately address the goal of public safety and creates a competitive disadvantage for private carriers who must bear this greater cost for security. EMS and private express carrier cargo are often loaded onto the same passenger aircraft, and therefore, the same security rules should be applied to EMS as private express carrier cargo.

## **Financial Services**

- Ensure the free flow of data. In the USMCA Financial Services Chapter, Article 17.19: Transfer of Information is a good example of a strong free flow of data provision that a U.S.-Japan trade agreement can draw upon. Similarly, a U.S.-Japan trade agreement should prohibit data localization measures. The USMCA Financial Services Chapter, Article 17.20: Location of Computing Facilities, prohibits data localization as long as financial institutions provide the access to data to regulators for their regulatory and supervisory purposes. Inclusion of such a provision in a U.S.-Japan trade agreement is critical to the affirmation of this U.S. government policy for the provision of financial services in a global economy. Combined, provisions 17.19 and 17.20 will help facilitate the adoption of cloud technologies in the Financial Services sector which will have multiple benefits for efficiency, cybersecurity, and privacy. While the U.S.-Japan Digital Trade Agreement contains strong language in these areas, it is important that similar language also be included in the financial services chapter of any comprehensive U.S.-Japan Trade Agreement.
- A U.S.-Japan trade agreement should commit to deepened regulatory cooperation and coherence in FinTech developments, complementing multilateral and other bilateral efforts aimed at promoting cross-border financial technology development and growth.
  - Financial regulatory cooperation commitments in a U.S.-Japan trade agreement should include robust transparency obligations that ensure stakeholders have the opportunity to review and comment on proposed measures. Such obligations would ensure industry and other stakeholders can engage with regulators to craft meaningful outcomes to meet regulatory objectives while not hindering the industry's ability to serve its clients. The agreement should also set clear rules regarding how regulators will engage with applicants for a license, including timelines and fees.
- A U.S.-Japan agreement should set a high standard to discipline subsidies to financial services related entities. Provisions in the financial services chapter should discipline the granting of subsidies to state-owned financial institutions with limited exception for certain programs.
- Encourage the U.S. and Japanese governments to avoid distortions that arise when one market participant enjoys favorable treatment over another.
  - Establish a level playing field between mutual aid cooperatives (*kyosai*) and Financial Services Agency (FSA)-regulated private sector financial service providers.
  - Support the Japanese government's continued efforts to ensure a level playing field between postal financial institutions and the private sector.

## **Functional Foods and Dietary Supplements**

- A U.S.-Japan trade agreement should ensure science-based risk assessments that align chemical assessment methods and promote alignment in classification and labeling. Authorities should be required to include U.S. companies in consultations on ingredients that will be impacted by evolving regulations.

- Both governments should agree to adopt and accept internationally recognized standards, including Good Manufacturing Practices (GMPs).
- As a general principle, regulations should be risk-based, evidence-based and incorporate cost benefit analysis.
- Both governments should agree to no duplication in testing or approval requirements and an acceptance of a manufacturer's Declaration of Conformity.
- The accord should mandate science-based risk assessments and mutual recognition for vitamin and mineral levels as well as the acceptance of botanicals in food supplements.
- Rules of origin should be consistent with those proposed in the original version of the TPP. The initial TPP rules provided for a 10 percent *de minimis*. Furthermore, the exceptions to *de minimis* did not prevent the use of foreign material in production of the finished products under tariff subheading 2106.90.

### **Government Procurement**

- The bilateral negotiations should provide for open, transparent, and reciprocal access to U.S. and Japanese procurement markets, expanding access beyond the level established in the WTO's Agreement on Government Procurement.

### **Intellectual Property**

Many American companies, like those in the creative content industry and the biopharmaceutical sector, among others, depend on intellectual property. In order for U.S. industries to continue to thrive, the U.S. government must ensure that the United States' trading partners are putting in place effective intellectual property (IP) protection and enforcement mechanisms to protect U.S. companies operating abroad. We urge the U.S. government to ensure that such protections are secured as early in the negotiation as possible.

- Provisions should include a strong base term and scope of protection for patents, copyrights, trademarks, designs, and establishment of a statutory commitment to protect trade secrets; exclusive rights for all forms of IP regardless of business models; transparent, predictable, and carefully-defined rules for exceptions to rights across all forms of IP.
- On copyrights, the agreement should require parties to provide effective remedies for online copyright infringement, including intermediary liability, with appropriately conditioned liability safe harbors for intermediaries.
- American companies are widely recognized as global leaders in technology innovation. The licensing of these IP assets has increased global access to innovative technology, created high value jobs and resulted in billions of dollars of economic growth. To support the licensing of technology, this agreement should prohibit government interference in commercial negotiations between private parties related to legitimate IP.
- On trade secrets, civil and criminal causes of action and penalties for trade secrets theft are critically important.
- IP enforcement measures should also include ensure fully effective injunctive relief; deterrent-level civil and criminal remedies in law, backed up by effective enforcement efforts, including ex-officio authority to seize goods and enforcement for goods trans-shipped through a party's territory in order to combat trade in counterfeit goods.

## **Investment**

- It is important that any U.S.-Japan trade agreement endorse and enhance the economic strength each country receives from the private sector's cross-border investments. The agreement must reject any effort to unwind supply chain investments in goods and services.
- The obligations found in the U.S. 2012 model Bilateral Investment Treaty text should serve as the basis for an investment chapter in a prospective U.S.-Japan trade agreement. The agreement should protect U.S. and Japanese investments from non-discriminatory treatment, direct and indirect expropriation, under the minimum standard of treatment, including fair and equitable treatment, performance requirements and ensure free transfers. These obligations should be enforced via investor-state dispute settlement (ISDS) provisions, which provide for neutral arbiters to uphold these investment protections. The agreement should ensure that all sectors are afforded the same level of protection.
- A U.S. trade agreement should prohibit measures that would require a financial institution to purchase or use a particular technology and include protection from such a performance requirement for all sectors, including financial institutions.
- Financial institutions must invest abroad to serve customers and clients and, in doing so, make significant investments under the prudential regime of the trading partner. These investments should be afforded the same level of protection in a U.S.-Japan trade agreement as other investments.
- It is the Chamber and USJBC's view that the USMCA text should not be drawn on in this chapter as it represents a notable step back from the investment protections included in many U.S. trade agreements and bilateral investment treaties.

## **Pharmaceutical and Medical Devices**

Based on the long-history of detailed bilateral trade talks on pharmaceutical and medical device market access, we look to the two governments to achieve a comprehensive agreement in these sectors that includes pricing and reimbursement, intellectual property rights, and regulatory convergence. To meet these goals, the bilateral talks should aim to:

- Provide greater transparency and due process, including regular and meaningful opportunities to provide input regarding the development of further reforms to the pricing and reimbursement system.
- Maintain long-established biennial review of reimbursement prices for innovative products, rather than move to an annual review under the National Health Insurance (NHI) system.
  - For pharmaceuticals, any off-year pricing revisions should not target all pharmaceutical products but rather should be limited to those products for which there is a large percentage differential between the NHI-reimbursed price and the market price.
  - For medical devices, the rules governing biennial reviews should remain stable, with changes considered to better reward new and existing devices in robust consultation with stakeholders. Reforms to the process of consolidating functional categories should be considered with stakeholders.
- The New Health Technology Assessment (HTA) system, introduced in April 2019, should continue to be applied post-launch to validate a product's premium (allowing for both upward and downward adjustments) based on criteria and validated methodology that recognize the full value of innovative medicines as a whole. Cost effectiveness analysis and

appraisal processes should keep fairness and transparency through full involvement of critical stakeholders such as manufacturers and patients with the equal status of healthcare providers, payers and health economic specialists. Furthermore, upon completion and evaluation of the medical device HTA pilot, if HTA is applied to devices, such usage should be applied only in special cases after launch.

- Ensure meaningful regulatory convergence to reduce redundancies, and flexible use of expedited approval pathways to deliver innovative medicines earlier to patients.

#### Pharmaceuticals:

- Eliminate new company criteria and expand the product criteria within Japan's Price Maintenance Premium program (part of the pharmaceutical reimbursement system) to better value the contribution that innovative medicines and therapies bring to the Japanese healthcare system.
- Eliminate the Tokurei Kakudai Saisantei (special expansion re-pricing or huge-seller penalty), which cuts the price of a product purely on the ground that its sales have far exceeded the sales originally projected. This significantly penalizes and undervalues breakthrough therapies in an attempt to manage budget impact.
- Ensure that procedures and rules that apply to pharmaceutical pricing and reimbursement decisions are predictable and transparent: the intensive investment in the development of innovative medicines requires a predictable and transparent public policy environment that fosters medical advancements and a favorable business environment. This includes creating efficient and transparent processes for bringing new medicines and technologies to market, such as publishing rules related to pricing and reimbursement in advance of adoption, making decisions in a timely fashion, and allowing stakeholders meaningful opportunity to participate in the development of rules and regulations in the pharmaceutical sector.
- Adopt robust intellectual property protection and enforcement commitments that meet the highest global standards, including broad patentability, patent term restoration and adjustment, effective measures to permit resolution of pharmaceutical patent disputes prior to generic or biosimilar launch (sometimes referred to as "patent linkage"), as well as 12 years of regulatory data protection for biologics.

#### Medical Devices:

- Ensure transparency and procedural fairness in the process by which national health care authorities establish reimbursement for medical devices at the national level, including the consolidation of functional categories that underpin the reimbursement system. This would include a reasonable period of time for making reimbursement decisions, clear and publicly transparent rules that are used to make these decisions, consultations with applicants during the decision process, clear explanation of decisions made, and an appeals process for the applicants.