
Statement of
The American Chamber of Commerce in Japan

Prepared for
The Committee on Ways and Means
United States House of Representatives

Regarding "U.S.-Japan Trade Agreements"

December 4, 2019

Contact Information:
Anne Smith, U.S. Government Affairs
The American Chamber of Commerce in Japan
Masonic 39 MT Bldg. 10F
2-4-5 Azabudai, Minato-ku
Tokyo, Japan 106-0041
Email: asmith@accj.or.jp, external@accj.or.jp

The **American Chamber of Commerce in Japan (ACCJ)** has represented American business interests in Japan for over seventy years and has close to 3,500 members. On behalf of our members, we welcome the first stage trade agreement signed by the U.S. and Japanese governments on the digital economy, agriculture and industrial goods.

The ACCJ is encouraged by both governments' commitment to initiate the second stage of negotiations and to complete a comprehensive bilateral trade deal. The ACCJ believes that swift progress on a comprehensive deal is essential as it will allow the two countries to address additional outstanding trade issues, set platinum level standards for the Asia Pacific region in key areas, and promote future oriented products, services and technologies critical to jobs and investment in both countries.

The U.S.-Japan economic relationship is one of the largest in the world, with nearly $300 billion traded in goods and services in 2018. Immediate attention to outstanding market access and regulatory issues will ensure this bilateral relationship remains one of the strongest in the world. These efforts are essential to ensuring continued commercial opportunities for the most innovative sectors of both countries' economies, including life sciences, energy, manufacturing, fintech, and services.

A trade agreement between the U.S. and Japan would represent a significant step forward for one of the most important economic partnerships in the world and further American interests and strategic engagement in the Asia-Pacific region. Japan represents one of the largest markets outside of the United States for most key American industry sectors, thereby facilitating the export of "Made in America" goods and services and supporting hundreds of thousands of workers here at home. By addressing long-standing issues as well as those that have recently emerged through trade negotiations, the U.S. government will promote opportunities for our companies in the world's third-largest economy, thereby increasing American exports, growing American jobs, and boosting American investment.

We encourage the United States to include future-oriented provisions in the comprehensive bilateral agreement that set the standard for the 21st-century economy, as the Administration has advanced in the recent U.S.-Mexico-Canada Agreement and seeks in other trade negotiations. Such provisions include efforts to promote innovation, strengthen intellectual property protections, encourage regulatory transparency and enhance competition. The two governments should further advance shared frameworks for the free flow of data, and complementary approaches to personal privacy and cooperation in enhancing cybersecurity by including the U.S.-Japan Digital Trade Agreement in the comprehensive bilateral deal. The U.S. and Japan also have a shared interest in adopting rules that have value far beyond any agreement by itself: creating a more level playing field by increasing transparency, fighting corruption, and establishing rules to address the challenge in the global marketplace from state- owned enterprises.

Finally, beyond its commercial importance as a destination market for American exports and investment, Japan is also an indispensable U.S. security and geopolitical ally in a critical part of the world. Japan is a key partner in advancing a range of American interests in the region, particularly under the Administration's Indo-Pacific Strategy, and is collaborating on energy security and efforts to promote the use of U.S. energy exports, promoting quality infrastructure development in emerging economies, and advancing a fair, transparent, and rules-based system for global trade and investment. Strengthening our trade and economic partnership will enable both countries to more strategically engage in the region and expand their influence around shared values. Discussions should recognize the enduring partnership between the U.S. and Japan and seek to complement the reforms that Prime Minister Abe has undertaken in Japan.

To support trade discussions as they progress, the ACCJ respectfully submits the following objectives:

**Address ongoing issues in key American goods export sectors**

While Japan represents the second largest market outside of the U.S. for several industry sectors, there are specific challenges that must be addressed around autos, pharmaceuticals and medical devices, and energy. These sectors have faced regulatory and market access barriers in recent years that have slowed or could potentially slow the progress of exports into Japan. Any bilateral agreement should address these issues and create a level playing field with fair and transparent rules, coupled with predictable and stable conditions.

**Bolster America's strong position in the services and IT sectors in Japan**

Japan is the third largest market for U.S. services exports, and the United States enjoys a $14 billion trade surplus with Japan in services. Trade negotiations can support market access for U.S. firms in industries with great potential to reach Japanese consumers, such as in financial services and electronic payment services. The future of the U.S.-Japan economic relationship will be driven by these and other emerging industries, as much of the growth potential for American exports, investment, and commercial opportunity in Japan will come from services-oriented trade. The U.S.-Japan Digital Trade Agreement should be included as a chapter in a comprehensive bilateral agreement to codify the commitments made by both governments and enable innovative offerings from the American services sectors to grow even faster in Japan. Doing so is of strategic economic importance to the United States and will bolster U.S. global leadership in these sectors. Continued efforts to expand U.S. services exports in Japan also will increase the services surplus, thus helping offset any deficit in goods trade and enhancing an already strong bilateral trade and investment relationship by fostering innovation.

**Incorporate the critical perspectives of the private sector**

The ACCJ appreciates the Administration's frequent outreach to our Chamber, welcomes this opportunity to comment, and hopes the Administration will continue to consult regularly with U.S. business in Japan throughout these negotiations to identify specific solutions to open the way for more U.S. exports to and commercial opportunities in Japan in these and other critical sectors.

**Build upon recent economic reform efforts by the Japanese government**

As a general matter, notwithstanding the exceptions noted herein, American businesses have achieved greater access to the Japan marketplace over the past several decades as a result of previous bilateral and multilateral trade negotiations and domestic Japanese reform efforts. The reform agenda being pursued by the Abe administration has yielded further improvements that could help grow the economy to the benefit of all. For that reason, we strongly support constructive U.S.-Japan trade negotiations that serve to help bolster Japan's recent growth and reform trajectory.

## Issue- and Sector Specific Priorities

The following is a list of issue- and sector-specific priorities of the American Chamber of Commerce in Japan. This list is in alphabetical order by issue area and sector and does not reflect 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. Leveling the regulatory playing field would improve the accessibility of Japan's automotive market and consequently allow U.S. manufacturers to introduce advanced products and services to the Japanese market more quickly.

### 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, force 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:

- The Ministry of Health, Labour, and Welfare (MHLW) should initiate a system to expedite registration for Quasi Drug (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. A step further would be to simplify the process by eliminating unreasonable regulations on non- active (excipient) ingredients. 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.
- Simplify the regulatory approval process by introducing an online product registration/notification system. Simply replacing physical submission with on-line submission by using the same current software would not bring meaningful impact to the industry. To drive real simplification and effort reduction, there is a need to revisit the formats and designs of software which create application dossier to allow different features (allowing change notification for multiple products at once, not requiring past dossier that has been submitted, etc.) The system should also allow notification/application information to flow to Customs that should streamline 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).
- 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.
- Product risk assessments should be science-based, particularly when evaluating chemical assessment methods and aligning product classification and labeling standards with international norms.
- A mutual-recognition protocol should be adopted to preclude the need to duplicate testing or approval requirements and an 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 ACCJ applauds the commitments made by the U.S. and Japanese governments in the U.S.-Japan Digital Trade Agreement. To guarantee that the commitments are codified in both the U.S. and Japanese legal systems, we urge USTR to integrate the Digital Trade Agreement into the final comprehensive agreement as a chapter. The United States-Mexico-Canada Agreement (USMCA) text offers an excellent example of a robust chapter on digital trade.

**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 network 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**

- We applaud the commitments made by the U.S. and Japanese governments in the U.S.-Japan Digital Trade Agreement to ensuring the free flow of data and prohibiting data localization measures. To guarantee that the commitments are codified in both the U.S. and Japanese legal systems, we urge USTR to integrate the Digital Trade Agreement into the final comprehensive agreement as a chapter. 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. 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. 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.

- 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.

**Legal Services**

- Streamline the application and approval process for foreign lawyers to be licensed as Gaikokuho Jimu Bengoshi by reducing the home jurisdiction practice requirement, by adhering to the July 2010 information and documentation requirements for submission and by eliminating requirements for information that is supplemental to licensing requirements.
- Eliminate discriminatory treatment of Gaikokuho Jimu Bengoshi in areas of branching, formation of legal entities, handling of arbitration and third country law issues, discipline, and law firm management.

**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 this sector 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. This has been lacking in steps taken by the Japanese government to date.
- Eliminate the 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, many of which come from U.S.-based companies.
- 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.
- 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 device HTA pilot, if HTA is applied to devices, such usage should be applied only in special cases after launch.
- Ensure transparency and procedural fairness in the process by which national health care authorities establish reimbursement for medical devices at the national level. This would require 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.
    - The current Foreign Average Price (FAP) rule should remain consistent to provide stability and predictability. Because the FAP is vulnerable to exchange rate fluctuations, a new rule to absorb those fluctuations should be considered.
    - Reducing the number of functional categories results in the inappropriate lumping together of products of various levels of innovation, leading to adverse reimbursement implications. As the MHLW continues to reduce the number of functional categories, they should consider consolidating categories in years when re-pricing is not scheduled. In addition, the following should be provided to ensure transparency and predictability:
        - clear reasons why certain categories are considered for consolidation
        - adequate time for discussion with MHLW, including time to properly prepare for discussion
        - clear information regarding process, including screening of candidate categories, timing of hearing, and notification of decision.
- 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, fair, and transparent processes for bringing new medicines and technologies to market, such as publishing detailed written rules related to pricing and reimbursement in advance of adoption, making decisions based on those clearly written rules in a fair and 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.
- Ensure meaningful regulatory convergence to reduce redundancies, and flexible use of expedited approval pathways to deliver innovative medicines earlier to patients.