# THE IMPACT OF TRUMP 2.0 ON THE PHARMACEUTICAL INDUSTRY

## — IMPLICATIONS FOR DRUG PRICING, MANUFACTURING, AND INTERNATIONAL COOPERATION —

Mika Kinoshita
Industrial Research Dept., Industrial & Social Studies Div.
Mitsui & Co. Global Strategic Studies Institute

## SUMMARY

- The second Trump administration, under its policy of "America First," has introduced drug pricing reforms, pharmaceutical tariffs, and substantial cuts to basic research funding in quick succession, compelling pharmaceutical companies operating globally to respond.
- As China continues to bolster its health diplomacy by supplying vaccines and addressing other international medical and public health issues, the United States' position of leadership in global public health is increasingly eroding amid its withdrawal from the WHO and cuts to international medical assistance.
- These shifts in US medical and healthcare policy may affect the revenue structure, supply chains, and research base of Japan's pharmaceutical industry, requiring Japanese pharmaceutical companies to demonstrate flexible, strategic adaptability in response to the increasingly uncertain environment.

## 1. OVERVIEW OF THE US ADMINISTRATIVE TRANSITION AND HEALTHCARE POLICY

### POLICY CONTINUITY AND DISCONTINUITY WITH THE BIDEN ADMINISTRATION

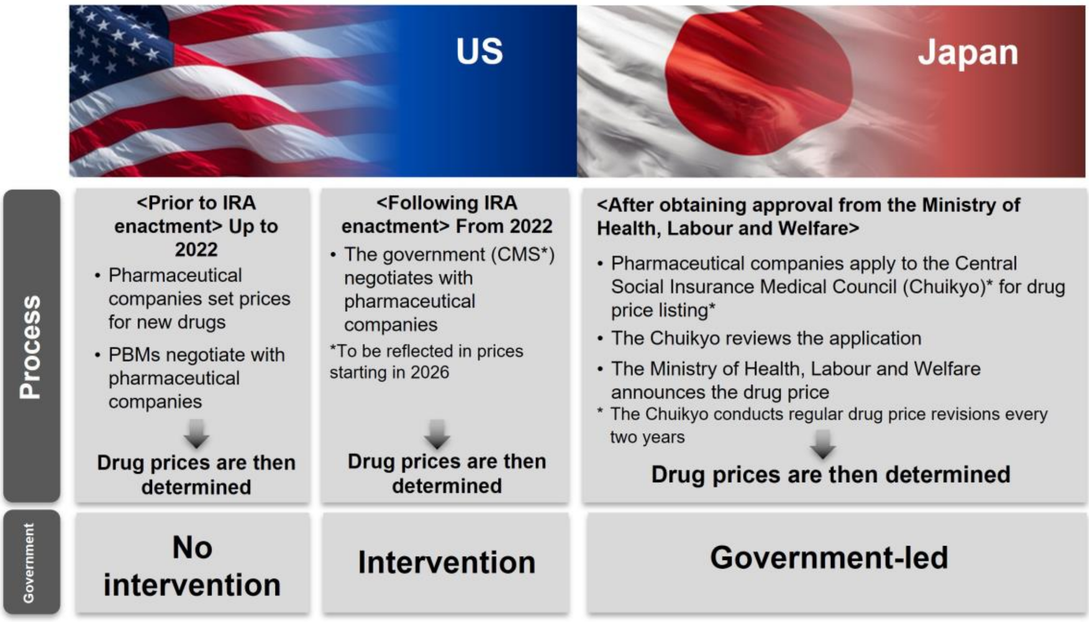
Reinstated in January 2025, the Trump administration has rapidly moved to overhaul medical and healthcare policies under the banner of "America First." To date, it has pursued measures such as redesigning the drug pricing system, promoting the reshoring of pharmaceutical manufacturing, and moving toward the introduction of tariffs on pharmaceutical products.

Under the Biden administration, efforts were made to improve patient access to healthcare and curb medical costs through a drug price negotiation system established under the Inflation Reduction Act (IRA) (Figure 1), as well as through reforms of pharmacy benefit managers (PBMs)[1]. For the first time, the US government was granted the authority to negotiate the prices of certain drugs, with phased price reductions scheduled to begin in 2026. While the Trump administration has maintained a general policy orientation toward drug price

[1] Pharmacy Benefit Manager (PBM): An intermediary operating under the US private insurance system that negotiates drug prices with pharmaceutical companies on behalf of insurers and employers, manages contracts with pharmacies, and oversees formularies of prescription drugs covered by insurance. Unlike in Japan and Europe, where governments directly regulate drug prices, the US has relied largely on market-based pricing, under which PBMs have played a central role in containing pharmaceutical costs. In the US market, a small number of large PBMs dominate and have exerted significant influence over both drug pricing and patient access to medications.

restraint, its institutional design and policy standards differ markedly. In particular, the Trump administration tends to link pharmaceutical policy with trade and economic security, positioning it as a tool for external negotiations. Notable examples include proposals to apply a most-favored-nation (MFN) drug pricing framework[2], which links US drug prices to the lowest levels among other developed countries, and the potential introduction of pharmaceutical tariffs (Figure 2).

**Figure 1: Drug pricing framework**




CMS*（Centers for Medicare & Medicaid Services）: The agency responsible for administering Medicare and Medicaid under the U.S. Department of Health and Human Services.
Central Social Insurance Medical Council* (Chuikyo): An advisory body to the Ministry of Health, Labour and Welfare that reviews and provides recommendations for setting medical service fees and drug price standards.
Drug price listing*: The inclusion of a pharmaceutical product in the drug price standards, making it eligible for insurance reimbursement (insurance coverage).

Source: Compiled by MGSSI based on various materials

[2] Application of the most-favored-nation (MFN) drug pricing: The most-favored-nation treatment principle—elements of which are currently being considered for application to the US drug pricing system—requires that the most advantageous trade terms granted to one country be extended equally to all other member countries. When incorporated into drug pricing policy, this concept would result in certain drug prices in the US being set by reference to the lowest prices among other developed countries. According to a May announcement by the US Department of Health and Human Services, reference countries are defined as those with per capita GDP at least 60% of that of the US and where pharmaceuticals marketed in the US are also sold, making Japan a potential candidate. However, the data sources to be referenced by the US government have not been disclosed, and the specific countries used for price comparisons remain unclear.

**Figure 2: Continuity and discontinuity in pharmaceutical policies under the Trump administration**

| Category | Policy | Biden administration 2021-2024 | Trump 2.0 From 2025 | Continuity/ Discontinuity | Key differences/Features |
|---|---|---|---|---|---|
| Drug pricing system | Medicare drug price negotiations | Selected target drugs based on the IRA and engaged in negotiations.<br><br>Application of agreed-upon prices: From 2026 | Selected the second round of target drugs in 2025 and continued negotiations (maintained the negotiation framework).<br><br>Application of agreed-upon prices: From 2027 | Continuity | May be combined with MFN treatment. |
| | Application of MFN treatment in the drug pricing system | – | Announced a policy via executive order in May 2025 to align domestic drug prices in the US with the lowest prices among other developed nations. Requested pharmaceutical companies to respond. | Discontinuity | Links trade policy with efforts and encourages higher drug prices abroad. |
| | PBM reform | Supported PBM transparency bills in Congress and state legislatures, backed by investigations and reports from the Federal Trade Commission. | Issued an executive order in April 2025 directing relevant agencies to establish rules that require PBM fee disclosure and promote competition. | Continuity | Means: Instructs regulatory agencies via executive orders to establish rules and advance institutionalization. |
| Drug prices | Drug tariffs | Pharmaceutical products (both finished drugs and active ingredients) remained exempt from tariffs. | | Discontinuity | Utilizes tariffs as a tool for drug price adjustments and bringing pharmaceutical manufacturing back to the US.<br><br>The scope of application and tariff rates remain fluid. |

In July 2025, Japan obtained MFN treatment for pharmaceutical tariffs under the U.S.-Japan Strategic Trade and Investment Agreement. In August of the same year, the EU set a 15% cap on pharmaceutical tariffs in a US-EU joint statement.
Exemption conditions*: Products manufactured by pharmaceutical companies currently constructing production facilities in the US, as well as companies that have announced new plant projects and initiated procedures to obtain approval from the Department of Commerce are exempt from the tariffs.
Source: Compiled by MGSSI based on various materials

At the same time, a marked discontinuity with the Biden administration is evident in health diplomacy—namely, diplomatic efforts to address global health challenges—illustrated by actions such as withdrawal from the WHO and reductions in international medical assistance (Figure 3).

**Figure 3: Continuity and discontinuity in bringing manufacturing back to the US and health diplomacy policies under the Trump administration**

| Category | Policy | Biden administration 2021-2024 | Trump 2.0 From 2025 | Continuity/ Discontinuity | Key differences/Features |
|---|---|---|---|---|---|
| Bringing manufacturing back to the US | Supply networks and security | Developed EO 14081* to bolster domestic manufacturing and supply networks. | Revoked EO 14081, and adopted a policy of excluding Chinese biotech companies from government procurement through renewed deliberation of the BIOSECURE Act. | Continuity | Means: Shifts from promoting industry to forcing return to the US through regulations and tariffs. |
| Health diplomacy | Participation in the WHO | Rejoined the WHO, and emphasized multilateral cooperation. | Issued an executive order in January 2025 directing a withdrawal from the WHO. | Discontinuity | Withdrew from multilateral cooperation. |
| | International medical assistance | Continued and enhanced international aid programs such as the President's Emergency Plan for AIDS Relief (PEPFAR)* | Promoted cuts to aid, though some programs survive due to opposition in Congress. | Discontinuity | Oriented toward budgetary and aid cutbacks. |

EO14081*（Executive Order 14081）: An executive order issued under the Biden administration to advance the US bio strategy. The aim was to strengthen the biotechnology sector (including manufacturing) as part of the United States' national strategy.
President's Emergency Plan for AIDS Relief (PEPFAR)*: A foreign aid program launched by the US in 2003 with the aim of preventing, treating, and providing support for HIV/AIDS. The program is active in more than 50 countries worldwide and is one of the largest US assistance initiatives in the field of global health.

Source: Compiled by MGSSI based on various materials

## 2. BUSINESS FOUNDATIONS OF THE US PHARMACEUTICAL INDUSTRY UNDER PRESSURE FOR REDESIGN

### 2-1. THE BIOSECURE ACT AND THE RETURN OF MANUFACTURING TO THE US

The BIOSECURE Act, which has remained under deliberation since the Biden administration, seeks to exclude five Chinese genome-related companies and contract development and manufacturing organizations (CDMOs), including WuXi AppTec and BGI Group, from federal procurement[3]. This policy direction has placed pressure on the global pharmaceutical industry to reorganize supply networks and shift manufacturing back to the United States. In the US, the procurement of active pharmaceutical ingredients (APIs) for generic drugs has become increasingly dependent on China[4], leading to the hollowing out of domestic manufacturing capacity. Moreover, China is involved in more than 20% of pharmaceutical products currently in the global clinical trial pipeline. In next-generation biopharmaceutical fields such as antibody-drug conjugates (ADCs)[5] and chimeric antigen receptor T-cell therapies (CAR-T)[6], more than half of the products are either of Chinese origin or jointly developed with Chinese partners, reflecting China's rapidly growing presence in research and development[7]. Under these circumstances, the abrupt exclusion of Chinese companies could expose vulnerabilities in pharmaceutical supply networks, potentially destabilizing supply, increasing costs, and delaying research and development.

The US-based Biotechnology Innovation Organization (BIO) has noted that many US biopharmaceutical companies rely on Chinese contract development and manufacturing organizations (CDMOs) for the procurement of active pharmaceutical ingredients (APIs), manufacturing, and support for research and development, and that replacing these suppliers or contractors would require a considerable amount of time[8]. Although the BIOSECURE Act has not yet been enacted, its passage would pose the risk that companies with business ties to Chinese firms could be excluded from US federal procurement. In light of these risks, major pharmaceutical companies have begun strengthening their supply networks and investing in manufacturing facilities within the United States (Figure 4). For generic drug manufacturers that have long depended on low-cost Chinese APIs amid intense price competition, shifting suppliers and investing in domestic manufacturing capacity would impose substantial burdens. Generic drugs account for 92% of all prescription medications in the US[9], and failure to secure a stable and affordable supply of APIs could further undermine the sustainability of the US healthcare system.

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[3] Federal procurement: The process by which the US federal government purchases or contracts for goods and services from external sources. All federal agencies are subject to the Federal Acquisition Regulation (FAR), which may also apply, where applicable, to procurement contracts for pharmaceuticals and other products and services.

[4] Dependence on China (for APIs used in generic drugs): According to a 2023 report by the US policy research institute the Atlantic Council, China has accounted for an average of approximately 17% of all pharmaceutical active ingredients imported by the United States over the past decade. However, for certain generic drug ingredients—particularly vitamins—more than 70% of supply originates from China. Furthermore, even in India, which accounts for roughly 40% of US API imports, approximately 70% of raw material inputs are sourced from China, underscoring the high level of indirect dependence on China.

[5] Antibody-drug conjugate (ADC): A next-generation antibody-based therapy that links cytotoxic agents to antibodies to selectively target cancer cells.

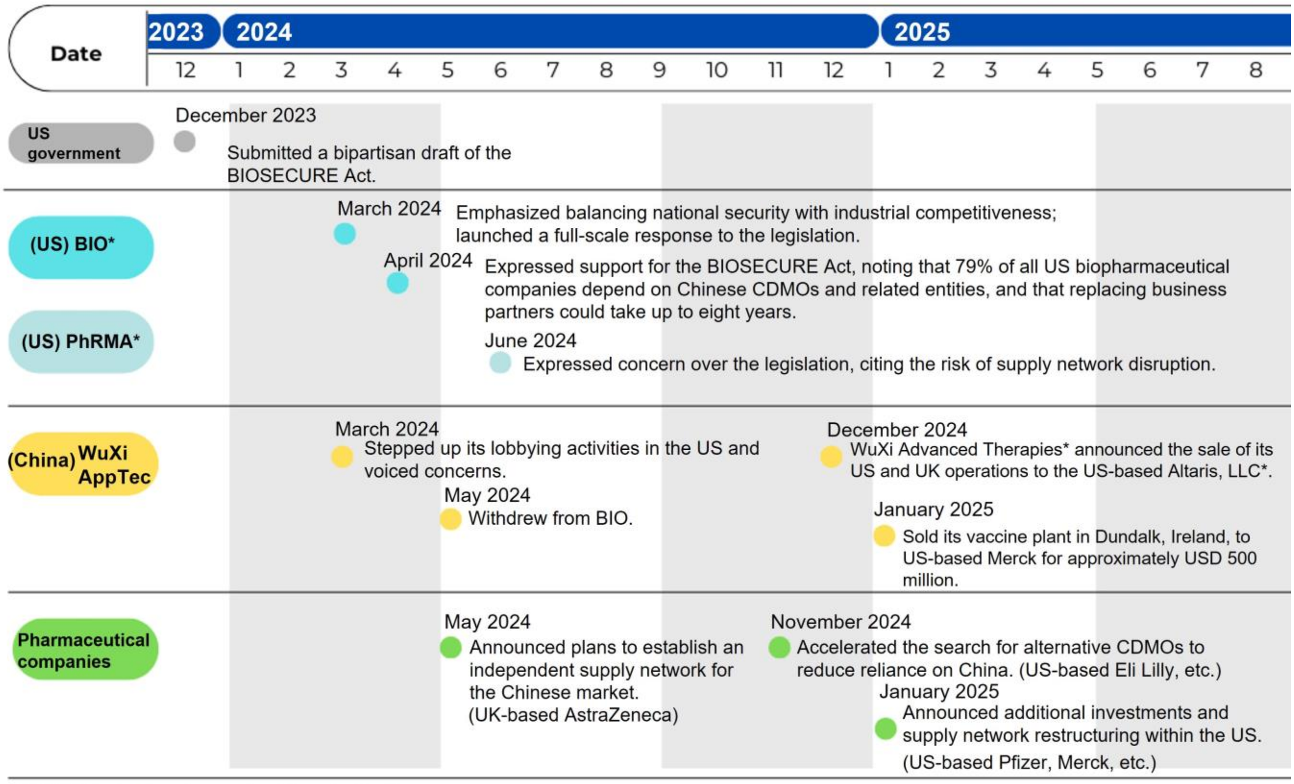
[6] Chimeric antigen receptor T-cell therapy (CAR-T): A form of cell therapy in which a patient's autologous T cells are collected and genetically engineered to recognize and eliminate cancer cells.

[7] Evaluate, 2025 Preview.

[8] According to a 2024 survey conducted by the US-based Biotechnology Innovation Organization (BIO), 79% of the 124 US biopharmaceutical companies surveyed have contracts with, or outsource manufacturing to, Chinese CDMOs or similar firms, and switching these contractors could take up to eight years.

[9] Association for Accessible Medicines, The U.S. Generic & Biosimilar Medicines Savings Report, September 2024.

**Figure 4: Developments relating to the BIOSECURE Act**




BIO* (Biotechnology Innovation Organization)
PhRMA*(Pharmaceutical Research and Manufacturers of America)
WuXi Advanced Therapies*: WuXi AppTec's cell and gene therapy unit
Altaris, LLC*: A healthcare investment firm
Source: Compiled by MGSSI based on various materials

## 2-2. IMPOSITION OF PHARMACEUTICAL TARIFFS AND INDUSTRY RESPONSES

The Trump administration announced that, beginning in October 2025, it would impose tariffs on pharmaceuticals as part of efforts to reassess the US pharmaceutical supply network—highly dependent on China—to strengthen domestic manufacturing, and to use tariffs as leverage in trade negotiations.

Global pharmaceutical companies headquartered in Ireland, which have long exported products to the US by leveraging low tax rates and advanced manufacturing infrastructure, initially faced concerns that high tariffs would undermine their cost competitiveness. However, in a US-EU joint statement issued in August 2025, the two sides agreed to cap tariff rates at 15%, allowing European pharmaceutical companies and global firms with manufacturing bases in the EU to avoid a major restructuring of their revenue models. Japan's pharmaceutical tariff rate is expected to remain on par with that of the EU, as the US-Japan Strategic Trade and Investment Agreement concluded in July includes the application of most-favored-nation treatment, linking Japan's tariff rate to the lowest rate imposed by the US on any other country.

These pharmaceutical tariffs also include exemption provisions. Products manufactured by companies that are currently constructing production facilities in the US, as well as those that have announced new plant projects and initiated approval procedures with the Department of Commerce, are exempt from the tariffs. Since the spring of 2025, as tariff risks have become more pronounced, pharmaceutical companies have been building up inventories within the US and investing in manufacturing facilities and other assets (Figure 5) to ensure a stable supply and maintain cost competitiveness.

**Figure 5: Investments in the US by major pharmaceutical companies**

| Company | Details of the announcement |
|---|---|
| (US) J&J | Over USD 55 billion over four years to establish three new manufacturing sites and expand existing facilities (Announced on March 21, 2025) |
| (US) Eli Lilly | USD 27 billion to establish four new manufacturing sites (Announced on February 26, 2025) |
| (US) AbbVie | USD 10 billion over ten years, with a portion allocated to establishing four new manufacturing sites (Announced on April 25, 2025 *Details undisclosed) |
| (Switzerland) Roche | USD 50 billion over five years to establish four R&D centers and one manufacturing site, and to expand existing facilities (Announced on April 22, 2025) |
| (Switzerland) Novartis | USD 23 billion over five years to build and expand ten facilities and enhance R&D capabilities (Announced on April 10, 2025) |
| (Japan) Takeda Pharmaceutical Company Limited | USD 30 billion over five years for investment in manufacturing sites and R&D (Announced on May 8, 2025 *Details undisclosed) |

Source: Compiled by MGSSI based on news reports

### 2-3. ADMINISTRATIVE REFORMS UNDERMINING US RESEARCH INFRASTRUCTURE

The Trump administration, in the name of fiscal consolidation and administrative efficiency, has pursued reforms affecting the life sciences research infrastructure, including staff reductions and budget cuts at federal agencies under the Department of Health and Human Services[10]. Research grants for US universities and research institutions have also been reduced across the board[11], leading to a sharp decline in the federal funding that has long supported basic research. As a result, researchers are increasingly leaving the United States, and a contraction in international collaborative research is anticipated. This trend threatens to weaken the US innovation base, which has long driven life sciences research globally, and could ultimately lead to a decline in the nation's drug discovery capabilities[12].

## 3. RETREAT IN INTERNATIONAL PUBLIC HEALTH AND HEALTH DIPLOMACY AND ITS IMPACT THEREOF

### 3-1. DECLARATION OF WITHDRAWAL FROM THE WHO AND THE RISK OF A BREAKDOWN IN GLOBAL PUBLIC HEALTH COORDINATION

In January 2025, the Trump administration once again[13] announced the country's withdrawal from the World Health Organization (WHO). Following this announcement, the administration began systematically removing public health data that the US government had previously made publicly available[14], undermining the leadership role the US had long played in global public health.

Meanwhile, China has been strengthening its health diplomacy by supplying vaccines and providing medical assistance to developing countries, steadily expanding its influence in international public health. As China's growing presence is expected to fill the void left by the US withdrawal from the WHO, concerns have been raised that political factors could influence decision-making processes under a China-led framework[15]. The weakening of the neutral, science- and data-based coordination framework could erode the effective functioning of international norms, potentially leading once again to delayed initial responses and inequities in vaccine distribution, as witnessed during the COVID-19 pandemic, and resulting in even greater disruption to efforts to control infectious diseases.

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[10] According to multiple reports, it was announced that approximately 10,000 employees at federal agencies—including the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC)—would be laid off and that half of their regional offices would be closed. A large-scale layoff was carried out on April 1. Including roughly 10,000 employees who accepted early retirement incentives, the total workforce reduction reached approximately 20,000 employees, equivalent to about one-quarter of all staff. This initiative was reportedly part of a broader plan advanced by the Department of Government Efficiency (DOGE), which was led by Elon Musk at the time.

[11] According to multiple reports, the NIH announced a policy to lower the indirect cost rate for research grants to universities from the previous national average of 27% to a uniform 15%, covering expenses such as infrastructure, IT, and personnel. In addition, a series of abrupt cancellations of previously approved grants were reported.

[12] L. Rafael Reif, President Emeritus and former President of the Massachusetts Institute of Technology (MIT), has warned that reforms to the research infrastructure under the Trump administration, including reductions in research funding, could weaken the pioneering research capabilities and foundational technological innovation of US universities and research institutions, posing the risk that the United States may lose its central position in global research networks. (Rafael Reif, America's Coming Brain Drain: Trump's War on Universities Could Kill U.S. Innovation, Foreign Affairs, May 2025) Early-stage drug discovery innovations are rooted in pioneering research and the development of foundational technologies, with US research institutions playing a central role in this process. Accordingly, destabilization of the research infrastructure could undermine the broader ecosystem supporting US drug discovery, which has long been built and sustained through robust federal funding.

[13] In late May 2020, during the first Trump administration, President Trump accused the WHO of being under China's influence during the COVID-19 pandemic and, in July of that year, initiated the process of withdrawal from the WHO. However, in February 2021, under the Biden administration, the withdrawal decision was reversed.

[14] From January to February 2025, 203 datasets—accounting for 13% of those published on the CDC website—were taken offline. Some of the datasets were later reposted after revising the terminology from "gender" to "biological sex," a change that reportedly reflects political intent (Disappearing Data at the U.S. Federal Government. N Engl J Med. 2025 Jun 26;392(24): e55.).

[15] Infectious Diseases and International Cooperation: What Is Needed to Respond to COVID-19? International Affairs, No. 695 (October 2020)

## 3-2. SUSPENSION OF INTERNATIONAL HEALTH ASSISTANCE BY THE US AND RETREAT IN HEALTH DIPLOMACY

The US has long played a leading role in global efforts to control infectious diseases, including the President's Emergency Plan for AIDS Relief (PEPFAR), polio eradication initiatives, and malaria prevention programs. However, the Trump administration has ordered that these programs be either suspended or substantially defunded. While some programs have continued due to opposition in Congress, concerns remain about the deterioration of healthcare systems in low- and middle-income countries (Figure 6).

The erosion of US health diplomacy would undermine its credibility and influence, further weakening healthcare systems in developing countries and increasing the risk of future pandemics. Ultimately, this could backfire by endangering the health of the American people in the future and sharply driving up the costs of crisis response.

**Figure 6: Past US contributions to global health and policy shifts under the Trump administration**

| Timing of launch and the administration at the time | Past initiatives | From 2025 Developments and impacts under the Trump administration |
|---|---|---|
| From 1948 Harry S. Truman (Democratic Party) | Led the US in joining the WHO at the time of its founding and promoted the inclusion of non-UN member states. | Announced withdrawal from the WHO, criticizing its response to the COVID-19 pandemic as "lacking neutrality." Formal withdrawal scheduled for January 22, 2026. |
| From 1967 Dwight D. Eisenhower (Republican Party) | Contribution to smallpox eradication efforts: Provided funding, technical assistance, and other aid for the WHO's global campaign. The WHO declared smallpox eradicated in 1980. | Withdrawal from the WHO and downsizing of the Centers for Disease Control and Prevention: Caused concerns over the weakening of international surveillance and response systems for similar infectious diseases and bioterrorism threats. |
| From the 1960s John F. Kennedy (Democratic Party) Lyndon B. Johnson (Democratic Party) | Support for polio eradication: Distributed vaccines, and provided technical assistance through the Centers for Disease Control and Prevention. | Withdrawal from the WHO and suspension of funding to the Vaccine Alliance (Gavi): Caused concerns over weakening the foundation of the polio eradication initiative*, which is now in its final stage. |
| From 1978 Jimmy Carter (Democratic Party) Ronald Reagan (Republican Party) | Support for the development of oral rehydration therapy: Funding enabled scientists in South Asia to develop and disseminate the therapy. This led to a significant reduction in child mortality due to severe dehydration from diarrhea. | Withdrawal from the WHO, dismantling of USAID*, and suspension of funding to Gavi: Caused concerns over the weakening of basic preventive healthcare and hygiene education systems in developing countries. |
| From 2000 Bill Clinton (Democratic Party) | Support for Gavi: The US was a major donor to Gavi, which is estimated to have saved 19 million children's lives, at the time of its establishment. | Suspended funding. |
| From 2003 George W. Bush (Republican Party) | Establishment of PEPFAR: The program supported HIV/AIDS prevention and treatment initiatives in developing countries, saving more than 26 million lives. | Caused concerns over the suspension of PEPFAR and the scaling back of HIV/AIDS-related assistance. |

Final stage of the polio eradication initiative*: At present, only two countries—Afghanistan and Pakistan—remain endemic for wild poliovirus type 1.
USAID（United States Agency for International Development）*: An independent agency that specializes in foreign assistance (development aid), including public health and humanitarian support provided by the US government.

Source: Compiled by MGSSI based on various news reports and data

## 4. FUTURE PROSPECTS: PREPARING FOR THE CHANGING BUSINESS ENVIRONMENT

If the Trump administration enacts all of its policies, the pharmaceutical industry will inevitably be required to respond to regulatory changes and the restructuring of supply networks, which could ultimately lead to a depletion of early-stage drug discovery innovations over time.

### 4-1. IMPACT ON JAPAN'S PHARMACEUTICAL MARKET

The Trump administration's policies are expected to affect Japan's pharmaceutical market in four main ways (Figure 7). First is the impact of drug pricing policy. If Japan's low drug prices are used as a reference in the new drug pricing system under consideration by the Trump administration, US drug prices could decline sharply, dealing a significant blow to companies that have relied on the US market for profitability. In other words, companies whose drug sales in Japan erode their profitability in the US may scale back R&D investments in Japan or even withdraw from the Japanese market. Should this materialize, there is a risk that "drug loss"—a situation in which patients in Japan are unable to access new medicines—could expand.

Second is rising costs resulting from pharmaceutical tariffs. Tariff rates for both Japan and Europe have been capped at 15%, and the overall impact is expected to be limited, as many global pharmaceutical companies are exempted through investments in manufacturing facilities within the US. However, Japanese companies that lack production bases in the US are likely to face higher costs when exporting their products to the US market.

Third is the impact of the BIOSECURE Act and pharmaceutical tariffs on supply networks. If the BIOSECURE Act is enacted, companies that sell pharmaceuticals in the US while relying on Chinese CDMOs may be excluded from eligibility for US government procurement[16] and subsidies[17], requiring them to reassess their business partners. In addition, the imposition of tariffs is forcing companies that operate manufacturing facilities outside the US to restructure their supply networks.

Fourth is the impact of budget cuts on the US research infrastructure. Budget reductions at US universities and federal agencies such as the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) could lead to stagnation or contraction in international collaborative research, as well as delays in new drug reviews[18]. Japanese companies that rely on the US research base and clinical trial environment may therefore face a slower drug development timeline and reduced operational efficiency.

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[16] Government procurement (Japanese companies and US government procurement): Shionogi & Co., Ltd. has entered into a supply agreement with the Biomedical Advanced Research and Development Authority (BARDA) under the U.S. Department of Health and Human Services for the novel influenza antiviral baloxavir marboxil (brand name Xofluza). Such federal procurement contracts may fall within the scope of restrictions imposed by the BIOSECURE Act (U.S. Department of Health and Human Services, BARDA Press Release, 2019).

[17] Grant eligibility (Japanese companies and US federal grants): Takeda Pharmaceutical Company Limited participates in research on immune diseases and rare diseases through collaborative projects with the NIH and American universities, with NIH grants supporting aspects of these research activities. Participation in such collaborative research projects carries the risk of falling under the grant-related provisions of the BIOSECURE Act (NIH Grants Database, Takeda collaboration records; Takeda Pharmaceuticals official releases).

[18] The Congressional Budget Office (CBO) estimates that a 10% reduction in the NIH budget could delay FDA approvals of new drugs by as much as nine months. In addition, the Regulatory Affairs Professionals Society (RAPS) has cited this analysis, reporting that budget cuts could have a serious impact on the supply of new drugs. (Congressional Budget Office, Estimated Effects of NIH Budget Cuts on New Drug Approvals, July 2025; RAPS, CBO: NIH Budget Cuts, Slower FDA Reviews Would Have Major Impacts, July 2025)

**Figure 7: Impact of the Trump administration's policies on Japan's pharmaceutical market**

| Trump administration policies | Primary impact |
|---|---|
| Drug pricing policy | **Increased drug loss:** If Japan's low drug prices are used as a reference in the US and prompt global pharmaceutical companies to withdraw from the Japanese market, it could accelerate drug loss in Japan. |
| Drug tariffs | **Increased costs:** Pharmaceuticals exported to the US via overseas manufacturing bases will face higher costs. |
| BIOSECURE Act<br>Drug tariffs | **Supply network restructuring:** Supply networks are being restructured as a result of pharmaceutical tariffs and the review of business partners prompted by restrictions on the use of Chinese biotech companies under the BIOSECURE Act. |
| Budget cuts to research foundation | **Weakening of the research foundation:** Budget cuts at the NIH, FDA, and universities are stagnating international collaborative research projects and delaying regulatory reviews, leading to slower and less efficient development of new drugs. |

Source: Compiled by MGSSI based on various news reports and data

### 4-2. STRATEGIC RESPONSES REQUIRED FOR JAPANESE PHARMACEUTICAL COMPANIES

In light of these environmental changes, Japanese companies are required to take the following actions (Figure 8).

**(1)** **Risk analysis:** Continuously monitor developments in the US drug pricing system, the implementation of tariff policies, and forthcoming policy signals, while quantifying their potential impact on revenues and supply networks.

**(2)** **Diversify supply networks:** Reduce dependence on China and invest in US facilities to obtain tariff exemptions, while carefully assessing the associated risks. Distribute production and procurement across Japan, the US, and Europe to prepare for supply disruptions in specific regions. In addition, from a national security perspective, strengthen manufacturing capabilities in Japan to ensure a stable supply of pharmaceuticals.

**(3)** **Strengthening R&D frameworks:** In anticipation of a contraction of the US research base, enhance collaboration with research institutions in Japan and Europe through joint research projects and other partnerships to sustain the capacity for innovation.

**(4)** **Participate in international dialogue:** Engage in discussions on drug pricing systems and international procurement rules through industry associations, and more proactively communicate the perspectives and positions of Japanese companies to the international community.

"America First" policies could pose significant challenges to Japan's pharmaceutical industry, including higher costs, the restructuring of supply networks, and the weakening of the research base. Viewing these challenges as opportunities and adapting to an uncertain and evolving business environment will be a prerequisite for Japanese pharmaceutical companies to maintain their medium- to long-term competitiveness.

**Figure 8: Responses required of Japan's pharmaceutical industry**

| Trump administration policies | Responses required of Japan's pharmaceutical industry |
|---|---|
| Overall measures | **Analyze risks:** Monitor developments in systems and policies such as drug pricing and pharmaceutical tariffs, and quantitatively assess their impact. |
| Drug tariffs | **Restructure and diversify supply networks:** Establish sites primarily in Japan, Europe, and the US to mitigate the risks of supply network disruptions and cost increases in specific regions, while ensuring a stable supply in Japan. |
| BIOSECURE Act<br>Budget cuts to research foundation | **Enhance R&D capabilities:** Strengthen collaboration with research institutions in Japan and Europe to maintain the foundation for innovation. |
| Overall measures | **Participate in international discussions:** Communicate Japan's viewpoints to the global community through industry associations and other channels. |

Source: Compiled by MGSSI based on various news reports and data