



STATEMENT ON ANNUAL PRICE REVISIONS
U.S.-Japan Business Council
June 9, 2014

The U.S.-Japan Business Council (USJBC) recognizes that Japan's attractiveness as a market for pharmaceuticals and medical devices has improved significantly in recent years, and commends the Government of Japan for its efforts to improve the regulatory, pricing, and product approval processes. However, the USJBC has serious concerns that ongoing discussions in the Council on Economic and Fiscal Policy regarding a proposed change from biennial to annual pharmaceutical reimbursement revisions under Japan's National Health Insurance system would undermine the positive steps taken. Such a change, if enacted, would have a severe impact on the environment for healthcare innovation and the ability of the Abe government to achieve its growth objectives in these important sectors.

More specifically, the USJBC urges the Government of Japan to refrain from implementing annual revisions for the following reasons:

- **Corporate Competitiveness and FDI:** The Third Arrow of Prime Minister Abe's economic growth strategy identifies the innovative pharmaceutical and medical device industries as key drivers of economic growth. A move to annual reimbursement revisions would create added unpredictability and instability in the healthcare services and manufacturing sector. This would have an adverse impact on Japanese and foreign pharmaceutical and medical device firms that contribute significantly to Japan's biomedical industry through high value-added research and development, employment, exports and intellectual property related licensing revenues, and introduction of new medical treatments that can save and improve the quality of lives. Moreover, it would also undermine the ability of domestic companies to remain and/or become more competitive as exporters of pharmaceutical and medical devices products globally. Annual revisions would also detract from years of progress made by the Japanese government in expediting drug and device approvals, streamlining regulatory processes, and improving the clinical trials environment, initiatives that have helped create an environment more attractive to foreign investment in the healthcare sectors.
- **Coordination with Medical Fee Schedule:** Medical fees and drug prices are currently revised simultaneously. A move to annual revisions would create misalignment in the overall healthcare reimbursement environment.
- **Accuracy of Reimbursement Rates:** Revision of reimbursement rates involves an extensive survey of individual drug and device prices in the market. Accurate identification of market prices within a short period of time would be extremely difficult to collect and would place considerable added burden on industry and healthcare professionals.

As Prime Minister Abe continues to move forward with an impressive economic growth agenda, the USJBC urges the Japanese government to consider carefully the implications of annual reimbursement revisions in the context of Japan's broader and longer term goals to attract investment and increase R&D in Japan, stimulate the healthcare sectors, and make leading edge clinical care available to Japanese patients.