

**SUPPLEMENT TO THE JOINT STATEMENT
HEALTH CARE INNOVATION
December 2, 2011**

The R&D-based pharmaceutical and medical device industries can contribute more significantly to the health and welfare of the peoples of the U.S. and Japan as well as to their economies. The Councils encourage both governments to actively pursue policies in these sectors that spur innovation and employment. Accordingly, the Councils offer the following specific recommendations and assessment of progress towards these goals:

Recommendations: Pharmaceuticals

1. **Improve the R&D Process:** The Councils welcome and encourage the Japanese Government's efforts to support Japan's participation in simultaneous global development. Japan's early participation in global development will prevent a future drug-lag from occurring. The Councils welcome and encourage Japan's participation in the "Tripartite" exercise with China and Korea to encourage the acceptance of Asian clinical data to support product approval in all three markets without having to conduct redundant clinical trials. The Councils urge Japan to continue showing leadership in promoting regulatory convergence with China and Korea on how to conduct Asian clinical trials in ways that allow smooth acceptance of the resulting data. For the realization of the above recommendation the Councils call on Japanese government to pursue reforms to enhance the Clinical Trials Network, implement improvements in the clinical trial environment by, for example, utilizing IT and supporting early/exploratory clinical trials.

The Councils encourage the Japanese government and the US FDA to engage in dialog with each other and with the CHMP to minimize redundant trials due to differing requirements on endpoints and trial design as well as to reduce the time required to reach agreement across the three Agencies on development programs.

The Councils encourage the US FDA to develop proper benefit/risk models to assist in balanced, consistent regulatory decisions. The Councils also encourage that new safety information communicated by US FDA also require information to be communicated on the product benefits, similar to the fair balance of risk information required by sponsors when communicated to prescribers and patients about their products.

The Councils continue to support the FDA's dialogue with the industry under the Critical Path Initiative, and look forward to concrete outcomes that will streamline the drug development process.

2. **Eliminate the Drug Lag:** The Councils continue to place great importance on the Pharmaceutical and Medical Device Agency's (PMDA's) undertaking to reduce new drug review times to 12-months total time by April 1, 2012. We welcome the shortening of review times for new drugs, and urge PMDA to shorten the review times for supplemental

applications, such as addition of indications. The Councils call on PMDA to build on the positive trend in new drug review times by engaging with industry in the development of a new set of comprehensive goals for new and supplemental applications for the next five years. We also expect improvement of the level of the PMDA reviewers in the fields of cancers, vaccines and antibody drugs.

The Councils encourage improvements in the transparency and predictability of the application review process of the FDA as a part of the renewal of PDUFA, that improve meeting performance targets while continuing to ensure patient safety.

- 3. Improve the Pharmaceutical Pricing System:** The Councils welcome the experimental introduction by the Government of Japan in April 2010 of a new pharmaceutical pricing system aimed at supporting innovation by keeping drug prices stable during their patent or data exclusivity period. These positive steps make Japan's market more attractive for innovative pharmaceutical development and introduction. As such, the Councils strongly urge that this new pricing system be made permanent in 2012. The Councils also strongly oppose anti-innovative applications of the Special Repricing for Market Expansion Rule.

In the U.S. the Councils urge that healthcare reform be introduced in a manner that continues to draw on the market principle, and not impede innovation, patient and physician choice or economic growth. It is an infringement of the initial commitment to impose additional economic burden to pharmaceutical companies. It works against innovative growth.

- 4. Enhance IPR Protection:** The Councils recognize the Japanese implementation of 8-year data exclusivity (reexamination period), and that the exclusivity is secured up to 10-year for pediatric indications. In addition, the Councils encourage Japan to adopt a 12-year period of data protection for biologics.

In the U.S. the Councils welcome the Government to quickly implement the 12-year period of data exclusivity for biologics. In addition the Councils continue to recommend that the current 5-year data exclusivity period in the U.S. for small molecules be extended to ensure a similar data exclusivity period to that in place in Japan.

The Councils also welcome the new America Invents Act which includes the shift from first-to-invent system to first-to-file system that enables the U.S. and Japanese patent systems to be well harmonized.

- 5. Vaccine Policy:** The Councils recommend that the Japanese government act quickly on the recommendations on vaccines made by the MHLW Health Science Council's Immunization Subcommittee, including development of a basic immunization policy and progress on the transition of vaccines to become routine vaccinations. For the short-term, the Councils recommend that the Japanese government continue its funding for the vaccines covered by the 2011 supplemental budget and increase vaccines to be funded by

the Japanese government. The vaccines which are not currently categorized as routine immunized vaccines but recommended for routine vaccinations will be included. Considering the degree of equity for the health of children, it should eliminate the gap of vaccinations between the rich and the poor.

Further, the Councils recommend that the Japanese government establish a committee to evaluate every new innovative vaccine in a timely and transparent way to determine whether that vaccine should receive recommended status, as well as a permanent funding system once vaccines receive recommended status. The Councils also recommend that the post-regulatory approval process be streamlined to accelerate public access to new vaccines, and that the government of Japan establish a formal national tracking system to evaluate efficacy and safety of the recommended vaccines after they are provided to the public.

Recommendations: Medical Devices

- 1. Regulatory Reform, Including PAL Revision & 510(k) Reform:** Over the past few years the Councils have recommended revision of Japan's unique regulations for Medical Devices. While efforts such as execution of the "Action Program" and revision of clinical research rules have been made within the current legal framework, the results were not always satisfactory. For example, performance improvement of product review cycles for "improved product categories" or "Me-too product categories" have not met the intended objectives. In addition, progress has not been made to change the scope of "partial change Shonin" requirements in case of product improvements such as Kairyō or Kaizen. With the current revisions to the Pharmaceutical Affairs Law, the Councils request that the law describe the concept of "rapid introduction of new product" and "contribution to innovation" under its objective clause.

The law should clearly define regulations that better reflect the characteristics of Medical Devices (reference best practices from other developed countries).

The items listed below are the requests submitted to the Government:

- To establish a regulatory framework which well reflects the fundamental difference from pharmaceutical products
- To allow those products which are not categorized as "brand new" to go through Ninsho program under third party reviewers
- To expand the scope of changes where the process for "partial amendment Shonin review" is not necessary
- To separate the product approval process / procedure and the QMS auditing
- To allow third parties to conduct QMS auditing
- To clarify the rules for clinical research

Also, the Council request to continue discussions for clarifying the legal responsibility regarding the consequences of product reviews.

As for the efforts being made in the U.S. to revise the rules for pre-market clearance system (510k), the Councils request that attention be paid so that the new system or its operations should not result in extending the product evaluation process. The Councils also request further efforts to be made to expedite the cycle time for PMA/510(k) approval.

- 2. Evaluation of Innovations:** The Councils appreciate the on-going effort to improve the evaluation of innovation at the reimbursement system discussions, for example the improvement of Advanced Medical Treatment Evaluations program and appointment of designated institutions for clinical research activities. The Councils continue to request that discussions between Government and industry be held in order to make progress in the evaluation of innovation including enhancement of the premiums for C1 or C2 products, and the transition to product-based, market-oriented pricing as well as the issues for reimbursement system revision for 2012 and beyond. The Councils point out the necessity to eliminate the Foreign Average Pricing system (FAP) for Medical Devices which was introduced in 2002. The pricing system should not be strongly influenced by sharp short-term foreign exchange rate fluctuations that may not reflect long-term economic fundamentals. Also, we oppose potential reforms of the Foreign Average Price rule such as the addition of Australia to or the removal of the high price country from the average.

The Councils strongly request that consideration be given to repealing the U.S. Medical Device tax commencing in 2013 so that it will not undermine the industry's activities for developing innovative products and therapies. The Councils also request additional careful consideration of all measures and programs designed to manage healthcare expenditure so that they do not hinder the potential clinical and economic benefits arising from Medical Devices.

- 3. FDA-MHLW Cooperation:** The Councils would like to see further collaboration and cooperation for joint projects between the regulatory authorities of the United States and Japan, and hope the authorities of the two countries have candid and positive discussions on the basic principles and framework for Medical Device regulations.
- 4. Medical Device Industry Promotion through Reconstruction Special Zone Measures:** The Councils support the development of a comprehensive plan within the Special Zone concept for Tohoku that includes the future model of the healthcare system, new medical services associated with Medical Devices, and concentration of R&D efforts in order to further advance the healthcare industry. The Councils anticipate that the development of a comprehensive plan will gain more interest and participation openly from domestic, U.S. and other overseas investors.