(Provisional Translation)

Statement by Mr. Katsuya Okada, Deputy Prime Minister of Japan and Minister in charge of Administrative Reform

10 July 2012

Today, the Cabinet of the Government of Japan decided on a "Policy on Regulatory and Institutional Reform," which notably includes a considerable number of measures addressing the interests of the EU, which is presently in a critical stage toward the launch of Japan-EU Economic Partnership Agreement (EPA) negotiations.

I am quite confident that this Cabinet Decision fully addresses the EU's requests or concerns on non-tariff measures in Japan, such as "Harmonization of automotive technical requirements and certification procedures with international standards," "Easing of the area size restrictions for automobile service shops," and "Streamlining and acceleration of the procedures for designation of food additives."

A crucial decision was made today toward the launch of the Japan-EU EPA negotiations.

As I believe that a Japan-EU EPA is extremely important for Japan and the EU, I sincerely hope that the EU will take proper account of a great effort made by the Japanese side and do its utmost toward an early launch of the Japan-EU EPA negotiations.

(Provisional Translation)

POLICY ON REGULATORY AND INSTITUTIONAL REFORM

CABINET DECISION
10 July 2012

HEREBY ADOPTED is "Policy on Regulatory and Institutional Reform" as attached, based upon the results of the examination conducted on regulatory and institutional reform by "the Committee on Regulatory and Institutional Reform" established under the Government Revitalization Unit (GRU).

For those items contained in the attached document, the relevant Ministries shall take measures in a prompt manner, and the Cabinet Office shall confirm and publish the contents of such measures and their progress quarterly.

1. Harmonization of automobile standards with international standards (1) (UN/ECE Regulations)

Outline of Regulatory and Institutional Reform

The Ministry of Land, Infrastructure, Transport and Tourism (MLIT) shall draft and publish a roadmap toward the adoption of UN/ECE regulations of which there is a substantial need for the adoption among the existing UN/ECE regulations, including assessing its validity and proposing necessary revision at the UN/ECE/WP 29, as part of efforts toward the realization of an International Whole Vehicle Type Approval (IWVTA) which are currently ongoing at the UN/ECE/WP 29, while taking into consideration safety and environmental protection in Japan.

→ **Timeline: Take measures in FY 2012.**

Measures to be taken (Law, Cabinet Order, Ministerial Order and Other Measures):

Other Measures

Responsible Ministry:

MLIT

2. Harmonization of automobile standards with international standards (2) (Gas container)

Outline of Regulatory and Institutional Reform

- The Ministry of Economy, Trade and Industry (METI) shall examine issues and decide on actions to be taken concerning regulations such as the *High Pressure Gas Safety Act and Container Safety Regulations* (Ministerial Notice No. 50, 25 May 1966), so that fuel tanks which conform to Global Technical Regulations (gtr) be approved when gtr are established at the UN/ECE/WP29.

→ **Timeline:**

Examine issues and decide on actions to be taken promptly upon the establishment of Global Technical Regulations (expected to be completed in November 2012).

- With regard to high pressure gas tanks mounted in hydrogen fuel cell vehicles, METI shall cooperate with the relevant authorities of the EU to address this issue in a pragmatic manner, for instance through an *ad-hoc* bilateral arrangement to recognize each other's requirements and approval procedures, pending the adoption of the Global Technical Regulations (gtr) at the UN/ECE/WP 29.

→ **Timeline:**

Start examination in accordance with the establishment of Global Technical Regulations (expected to be completed in November 2012).

Measures to be taken (Law, Cabinet Order, Ministerial Order and Other Measures):
All levels of measures are considered.

Responsible Ministry:
METI

3. Expansion of the scope of self-confirmation of technical regulations conformity for radio equipment

Outline of Regulatory and Institutional Reform

The Ministry of Internal Affairs and Communications (MIC) shall examine, in cooperation with relevant associations, toward the expansion of the scope of special specified radio equipment, so that manufacturers and importers of radio equipment conduct self-confirmation of technical regulations conformity stipulated under the Radio Law with regard to specified radio equipment including wireless LAN, and decide on actions to be taken, while taking into consideration international trends.

→ **Timeline: Examine issues and decide on actions to be taken in FY 2012.**

Measures to be taken (Law, Cabinet Order, Ministerial Order and Other Measures):
Ministerial Order

Responsible Ministry:
MIC

4. Regulatory and institutional reform in the area of medical devices (1) (review of the system based upon the characteristics of medical devices)

Outline of Regulatory and Institutional Reform

The Ministry of Health, Labour and Welfare (MHLW) shall examine issues and decide on actions to be taken to establish new clauses in the Pharmaceutical Affairs Law, separately from clauses on pharmaceuticals, based upon the characteristics of medical devices, to establish a new "chapter" on medical devices, and to change the title of the Law, taking fully into account opinions from relevant stakeholders such as industrial associations on medical devices.

→ **Timeline:**

Examine issues and decide on actions to be taken in FY 2012

Measures to be taken (Law, Cabinet Order, Ministerial Order and Other Measures):

Law

Responsible Ministry:

MHLW

5. Regulatory and institutional reform in the area of medical devices (2) (acceleration of approval review process for medical devices)

Outline of Regulatory and Institutional Reform

- The Ministry of Health, Labour and Welfare (MHLW) shall examine issues and decide on actions to be taken toward establishing a new system of approval/certification utilizing private certification bodies covering medical devices such as generic medical devices among specially controlled medical devices, and the MHLW shall continue to examine the further expansion of the scope for which third-party certification bodies are to be employed.

→ **Timeline:**

Examine issues and decide on actions to be taken in FY 2012

Measures to be taken (Law, Cabinet Order, Ministerial Order and Other Measures):

Law

- The MHLW shall examine issues and decide on actions to be taken toward streamlining the approval review process through measures such as the employment of data used in the approval/certification application in foreign countries which have the same levels of standards as Japan such as the United States, the EU, Canada and Australia.

→ **Timeline:**

Examine issues and decide on actions to be taken in FY 2012

Measures to be taken (Law, Cabinet Order, Ministerial Order and Other Measures):

Other Measures

Responsible Ministry:

MHLW

6. Regulatory and institutional reform in the area of medical devices (3) (Rationalization and acceleration of approval procedures for partially changed medical devices

Outline of Regulatory and Institutional Reform

The Ministry of Health, Labour and Welfare (MHLW) shall conduct intensive examination for expanding the scope of the changes of medical devices that do not require approval for partial change, and for streamlining approval procedures for partially changed medical devices, taking into consideration requests from relevant industrial organizations, then take measures to promote improvement and amelioration of medical devices in a prompt manner.

→ **Timeline: Take measures in FY 2012.**

Measures to be taken (Law, Cabinet Order, Ministerial Order and Other Measures):
Other Measures

Responsible Ministry:
MHLW

7. Regulatory and institutional reform in the area of medical devices (4) (Enhancement of international harmonization and streamlining of QMS audits)

Outline of Regulatory and Institutional Reform

- The Ministry of Health, Labour and Welfare (MHLW) shall examine issues and decide on actions to be taken toward the revision on the QMS Ministerial Order with a view to further improving the harmonization with international standards.

→ **Timeline:**

Examine issues and decide on actions to be taken in FY 2012.

- The MHLW shall examine and decide on actions to be taken on the revision of the current system of product-by-product QMS audits with a view to conducting QMS audits based upon for instance a manufacturing site or groups of products, in cooperation with associations of manufacturers and others.

→ **Timeline:**

Examine issues and decide on actions to be taken in FY 2012.

- The MHLW shall examine issues and decide on actions to be taken toward implementing measures to address issues of duplications of QMS audits in terms of document reviews and on-site audits by sharing results of QMS audits among different audit agents.

→ **Timeline: Examine issues and decide on actions to be taken in FY 2012.**

- The MHLW shall examine issues and decide on actions to be taken toward further streamlining of the QMS audit system, including the possible convergence of audit agents to registered certification bodies specializing, irrespective of risk classification of medical devices.

→ **Timeline: Examine issues and decide on actions to be taken in FY 2012.**

Measures to be taken (Law, Cabinet Order, Ministerial Order and Other Measures):

Law

Responsible Ministry:

MHLW

8. Regulatory and institutional reform in the area of medical devices (5) (Improvement of "certification" system of medical devices)

Outline of Regulatory and Institutional Reform

The Ministry of Health, Labour and Welfare (MHLW) shall examine issues and decide on actions to be taken, after conducting hearings from certification bodies and industrial associations concerned, on the possibility of the following measures under the Pharmaceutical Affairs Law:

With regard to a person who acquired marketing certification of medical devices on a product-by-product basis ("acquirer of certification"), when inheritance, merger or divestiture (limited to divestiture by which materials regarding the product concerned are succeeded) occurs, the inheritor, the judicial person that survives or is incorporated following the merger, or the judicial person that succeeds materials regarding the products concerned following the divestiture, succeeds the status of acquirer of certification;

When the acquirer of certification transfers materials regarding the products concerned, for the purpose of transferring the status of acquirer of certification, the transferee succeeds its status, and in such a case, also changes the certification body from which certification was originally acquired.

→ **Timeline:**

Examine issues and decide on actions to be taken in FY 2012.

Measures to be taken (Law, Cabinet Order, Ministerial Order and Other Measures):

Other Measures

Responsible Ministry:

MHLW

9. Regulatory and institutional reform in the area of medical devices (6) (Omission of package insert "Tempu-Bunsyo" of medical devices)

Outline of Regulatory and Institutional Reform

The Ministry of Health, Labour and Welfare (MHLW) shall examine issues and decide on actions to be taken toward deregulating the obligation to package insert *"Tempu-Bunsyo"* to medical devices, including the abolition of *"Tempu-Bunsho"* with prescribed formats.

→ **Timeline:**

Examine issues and decide on actions to be taken in FY 2012.

Measures to be taken (Law, Cabinet Order, Ministerial Order and Other Measures):

Law

Responsible Ministry:

MHLW

10. Regulatory and institutional reform in the area of medical devices (7) (Clarifying the position of stand-alone medical software in laws and regulations)

Outline of Regulatory and Institutional Reform

The Ministry of Health, Labour and Welfare (MHLW) shall examine issues and decide on actions to be taken on the status of stand-alone medical software under laws and regulations, including clarification that stand-alone computer-aided diagnosis software shall be classified as medical device.

→ **Timeline:**

Examine issues and decide on actions to be taken in FY 2012.

Measures to be taken (Law, Cabinet Order, Ministerial Order and Other Measures):

Law

Responsible Ministry:

MHLW

11. Streamlining and acceleration of the procedures for designation of food additives

Outline of Regulatory and Institutional Reform

- With regard to the undesignated 15 food additives among the "internationally commonly used food additives," the Food Safety Commission and the Ministry of Health, Labour and Welfare (MHLW) have already commenced the reviews of all the food additives based upon the measures taken for *"streamlining and acceleration of the procedures for designation of food additives,"* as set out in *"Policy on Regulatory and Institutional Reform"* (Cabinet Decision on 8 April 2011). The MHLW shall designate within FY 2012 the three food additives for which the Food Safety Commission has completed its assessment of their effects on human health.

  For the other 12 food additives, the Food Safety Commission and the MHLW shall, on the basis of increased resources for prompt designation, draft and publish a roadmap toward designation with ordinary period of one year or around, reflecting the time required for the already designated food additives, excluding time required for collection of further data and documents, then take actions.

→ **Timeline: Take measures by the end of the first half of FY 2012.**
(Designate the three food additives within FY 2012.)

Measures to be taken (Law, Cabinet Order, Ministerial Order and Other Measures):
Other Measures

- The Food Safety Commission and the MHLW shall examine the effects of the measures taken based upon *"Policy on Regulatory and Institutional Reform"* (Cabinet Decision on 8 April 2011) for the sake of *"streamlining and acceleration of the procedures for designation of food additives,"* and publish the findings.

→ **Timeline: Take measures in FY 2012.**

Measures to be taken (Law, Cabinet Order, Ministerial Order and Other Measures):
Other Measures

Responsible Ministry:
Cabinet Office (Food Safety Commission)
MHLW

12. Easing the area size restrictions for automobile service shops, based on land use zoning prescribed in the Building Standard Law

Outline of Regulatory and Institutional Reform

- The Ministry of Land, Infrastructure, Transport and Tourism (MLIT) shall investigate the situation of automobile service shops to examine whether the issue of the *Technical Guideline ("The application of approval based upon Article 48 of the Building Standard Law in relation to the establishment of automobile service shops [technical guidance])* (MLIT Circular Notice No.257, 31 March 2012) addressed to local government entities, has actually facilitated the establishment of automobile service shops of necessary sizes facing link roads, and publish its findings.

→ **Timeline: Take measures in FY 2012.**

Measures to be taken (Law, Cabinet Order, Ministerial Order and Other Measures):
Other Measures

- If the above-mentioned examination shows that the establishment of automobile service shops of necessary sizes is not facilitated, MLIT shall investigate causes in cooperation with local government entities, based upon local government entities' authority for urban planning in line with local autonomy reforms, then examine and take necessary further measures toward facilitating the establishment of automobile service shops of necessary sizes, such as the amendment of the Building Standard Law and the facilitation of authorization process, while respecting local government entities' autonomy.

→ **Timeline:**
Start examination in FY2012, and take measures in FY 2013.

Measures to be taken (Law, Cabinet Order, Ministerial Order and Other Measures):
All levels of measures are considered.

Responsible Ministry:
MLIT

15. Regulatory and institutional reform in the area of pharmaceuticals (1) (Elimination of Vaccine Gap)

Outline of Regulatory and Institutional Reform

- The Ministry of Health, Labour and Welfare (MHLW) shall conduct revisions in a timely manner for already approved "Minimum Requirements for Biological Products" with a view to ensuring consistency with international standards in terms of specifications and testing methods for vaccines.

→ **Timeline:**
Take measures in a timely manner starting from FY 2012.

Measures to be taken (Law, Cabinet Order, Ministerial Order and Other Measures):
Other Measures

- The Ministry of Health, Labour and Welfare (MHLW) shall examine issues for enhancing mutual environment between Japan and the EU and decide on actions to be taken, in order to exempt duplicate items among domestic requirements and in-house tests overlapping with overseas requirements for on release test, where the equivalence of GMP of the exporting country is perceived, while ensuring the system which enables Japan to verify directly the quality of vaccines manufactured in overseas manufacturing sites, with a view to resolving the overlaps in quality test when importing vaccines.

→ **Timeline:**
Examine issues and decide on actions to be taken in FY 2012.

Measures to be taken (Law, Cabinet Order, Ministerial Order and Other Measures):
Ministerial Order

- The Ministry of Health, Labour and Welfare (MHLW) shall examine and decide on actions to be taken toward expanding the scope of the Japan-EU MRA to products other than chemical pharmaceuticals, following the expansion of the MRA's country coverage.

→ **Timeline: Examine issues and decide on actions to be taken in FY 2012.**

Measures to be taken (Law, Cabinet Order, Ministerial Order and Other Measures):
Ministerial Order and Other Measures

- The Ministry of Health, Labour and Welfare (MHLW) shall examine issues and decide on actions to be taken in a timely manner on vaccines recommended by the WHO toward the introduction of routine immunization, while taking into consideration their safety, effectiveness and cost-effectiveness.

→ **Timeline:**
Examine issues and decide on actions to be taken in FY 2012.

Measures to be taken (Law, Cabinet Order, Ministerial Order and Other Measures):
Law

Responsible Ministry:
MHLW

16. Regulatory and institutional reform in the area of pharmaceuticals (2) (International harmonization of the GCP Ordinance)

Outline of Regulatory and Institutional Reform

- The Ministry of Health, Labour and Welfare (MHLW) shall examine issues toward the revision of the GCP Ordinance with a view to ensuring consistency of the GCP Ordinance with the contents of ICH-GCP Guidelines, and amend the Ordinance.

→ **Timeline: Take measures in FY 2012.**

Measures to be taken (Law, Cabinet Order, Ministerial Order and Other Measures):
Ministerial Order

- The MHLW shall examine toward ensuring consistency of the Notification on GCP Ordinance with the contents of ICH-GCP, and amend the Notification. In addition to the amendment of the Notification, the MHLW shall make public and ensure that the Notification shall be a guidance.

→ **Timeline: Take measures in FY 2012.**

Measures to be taken (Law, Cabinet Order, Ministerial Order and Other Measures):
Other Measures

Responsible Ministry:
MHLW

(Reference)

Cabinet Decision on 3 April 2012

Deregulation of emission regulations of passenger vehicles and commercial vehicles (Convergence of Japanese and the EU's emission gas regulations)

Outline of Regulatory and Institutional Reform

With regard to emission regulations of passenger vehicles and commercial vehicles, The Ministry of Land, Infrastructure, Transport and Tourism (MLIT) and the Ministry of Environment (MOE) shall promptly examine the possibility of the introduction of those regulations in Japan at the Central Environment Council and others, with a view to pursuing international harmonization, based upon discussion at the UNECE/WP 29 and others, and shall introduce international standards upon reaching conclusion.

→ **Time-line:** **Examine in FY2012 onward and take measures promptly upon reaching conclusion**

Measures to be taken (Law, Cabinet Order, Ministerial Order and Other Measures)
Other measures

Responsible Ministry:
MLIT
MOE