Comments on *Elements of a global strategy and plan of action*  
(A/PHI/IGWG/1/5) by the Government of Japan

The Government of Japan submits the following comments on *ELEMENTS OF A PLAN OF ACTION* in ANNEX 1 to the document A/PHI/IGWG/1/5. These comments similarly apply to discussions on *ELEMENTS OF A GLOBAL STRATEGY* in ANNEX 2.

1) “3. Promoting research and development,” Areas for action (a)

Regarding the phrase “larger or appropriate,” we prefer “appropriate.”

It is important for different players in the public and private sectors, including governments of developed countries, to cooperate to the extent possible under their own circumstances. Concerned organizations, including governments, are setting priorities and conducting research and development, taking account of various factors under their own circumstances. We think that allowing the flexibility to take into consideration these circumstances will lead to getting broader cooperation than placing restrictions on the direction of the budget.

2) “3. Promoting research and development,” Areas for action (e)

We would like to propose that the phrase “appropriate legal arrangements [to be defined] permitting unrestricted access to drug leads” should be amended to read “contractual arrangements permitting appropriate access to drug leads.”

What “legal arrangements” means can be interpreted in a broad way. It may refer to legislative amendments or contractual arrangements between individuals under national regulations. We think that contractual arrangements between individuals that permit appropriate access to drug leads will contribute to promoting the development of medicines.

3) “3. Promoting research and development,” Areas for action (g)

We would like to propose that the phrase “within the confines of Article 30 of the TRIPS Agreement” should be inserted after “consider legislation.”

Regarding “research exemption,” the interpretation or operation is not harmonized internationally, though many countries have such a provision. In considering “research exemption,” requirements to allow Article 30 of the TRIPS Agreement “Exceptions to Rights Conferred” should be noted. These requirements
are:
(1) the exception must be "limited"; (2) the exception must not "unreasonably conflict with normal exploitation of the patent"; (3) the exception must not "unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties". (WTO document WT/DS114/R, paragraph 7.20, Page 152)

4) “4. Building and improving innovative capacity,” Chapeau

We would like to propose that the phrase “subject to international obligations” be inserted after “framing of patenting and licensing policies.”

For the same reason as 3) above, compliance with other international obligations should be observed in consideration of framing of patenting and licensing policies including legislation on research exemption.

5) “4. Building and improving innovative capacity,” reference to the CIPIH recommendation 5.10

To prevent problems in which patents are granted erroneously despite a lack of novelty and inventiveness, we think that databases of traditional knowledge are useful. Establishing such a database will provide patent examiners with a situation that makes it easier to conduct prior art searches. Japan has already submitted a proposal to WIPO on the improvement of a database system. We support the idea of “digital libraries,” and hope for an expansion of the discussion in WIPO. In addition, in the discussion on traditional knowledge databases, it is necessary to respect the holders of such knowledge. However, whether to incorporate such a database into the “minimum documentation” should not be prejudged. First, we should consider what kind of database to develop. In addition, we think that it is appropriate to discuss this matter in WIPO.

6) “6. Management of intellectual property,” Areas for action (a)

We would like to propose that areas for action (a) should be replaced by the following, which is from operative paragraph 1. (2) of resolution WHA 56.27:

- consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

Each country has the right to use the flexibilities contained in the TRIPS Agreement. However, we think that whether to apply such flexibilities, or to what extent, should be determined circumstantially by each country. In addition,
membership to the WHO and WTO is not the same. There are WTO members that are entitled to avail themselves of a transitional period for application of the provisions of the TRIPS Agreement. Therefore, we think that it is not appropriate to use wording that mean to make obligatory legislation for application of the flexibilities.

7) “6. Management of intellectual property,” Areas for action (e)

   Education and training in research and development, including the management of intellectual property, is important in taking advantage of intellectual property and promoting research and development and technology transfer, and we support area for action (e).

8) “6. Management of intellectual property,” Areas for action (f)

   We would like to propose that area for action (f) should be replaced by area for action (g), which is from operative paragraph 2. (4) of resolution WHA 59.24.

   Bilateral trade agreements are agreed on through negotiations of interested parties, and each party decides on conclusion of an agreement, based on advantages and disadvantages of its contents. Restricting the contents of bilateral trade agreements is beyond the mandate of the WHO. Although the definition of TRIPS-plus is not clear, appropriate protection of intellectual property is a factor indispensable to the development of industry, including the pharmaceutical industry.

9) “7. Improving delivery and access,” Areas for action (m)

   We would like to propose that the phrase “in view of the leverage to determine prices that patents confer” should be deleted.

   This phrase gives the impression that a patent decides the price of a medicine. We believe that the price of a medicine can be decided based on not only patents but also other various factors.

10) “8. Ensuring sustainable financing mechanisms,” Areas for action (d)

    Regarding a funding mechanism, we believe that it is important to promote research and development efficiently, utilizing existing mechanisms such as TDR.

11) “9. Establishing monitoring and reporting systems,” Chapeau and Areas for action (a)

    We support empirically monitoring the impact of intellectual property rights on innovation and access to medicine. Although specific methods of monitoring are not
clear, practical methods should be used. From the perspective of feasibility, it is appropriate to focus on the development of and access to medicines for diseases that disproportionately affect developing countries. Then, we should consider what kind of medicines or technologies are needed, and study how intellectual property rights are established for them, and examine how such intellectual property rights have a positive or negative impact. In addition, we believe that it is necessary to consult with other international organizations with specialized expertise in the area of intellectual property.