Pandemic influenza A(H1N1) vaccine policy in Japan

Country: Japan
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Health Policy Issues: Public Health, Pharmaceutical Policy

Current Process Stages

1. Abstract

Pandemic influenza A(H1N1) vaccination in Japan has been run as a governmental project. In order to secure a sufficient amount of pH1N1 vaccine, the government enacted a new law of governmental compensation for death or health damages caused by pH1N1 vaccines and announced to issue exceptional authorization of production and distribution for two pH1N1 vaccines produced by international manufacturers.

2. Purpose of health policy or idea

As for pandemic influenza A(H1N1) 2009, timely and sufficient distribution of the pH1N1 vaccine was expected by health professionals and the public. The Japanese government has taken responsibilities to secure a sufficient amount of the vaccine covering the whole population and to guarantee to pay for expenses for harms caused by the vaccine which manufacturers usually take.

However, domestic production of the vaccine was estimated to respond short to the needs of the general population who seeks to get vaccinated. The Ministry of Health, Labour and Welfare (MHLW) announced that the estimated amount of domestic production of pandemic influenza vaccine was 2,540 vials (1ml/vial) by the end of 2009, according to the data of production of seasonal influenza vaccine in recent years. In addition, the proliferating ability of the pH1N1 antigen which was needed to produce the vaccine was uncertain. In order to fill the gap between the needs and the domestic production of pH1N1 vaccine, the Japanese government decided to enhance the capacity of productivity of domestic vaccine manufacturers and to import pH1N1 vaccine from other countries.

In December 2009, the Japanese government enacted bills into the Act on Special Measures concerning the Relief of Pandemic Influenza Vaccine-related Adverse Events. This Act stipulated that the Japanese government takes responsibility to pay for expenses for death or health damages caused by pH1N1 vaccine instead of vaccine manufacturers in order to promote production and import of the vaccine.

In general, authorization of production and sales of a new human biological product, e.g. vaccines, requires clinical trials in Japan which take a long time. However, in a state of public health emergency, on January 15, 2010, the Ministry of Health, Labour and Welfare offered an exception of requirement of clinical trials in Japan and authorized two import vaccines with reference to clinical trials in other countries, based on Article 14(3) of Pharmaceutical Affairs Act. This was the first authorization based on Article 14(3) of Pharmaceutical Affairs Act in history.
Main objectives
The Japanese government aimed:

1. to secure a sufficient amount of pH1N1 vaccine covering the whole population in Japan; and
2. to provide appropriate relief to patients suffering an adverse event due to pH1N1 vaccine.

Type of incentives
Financial incentives:

1. Exemption for domestic and international manufacturers from responsibility for paying expenses for death or health damages caused by pH1N1 vaccine
2. Governmental procurement of all pH1N1 vaccine sold in Japan.

Non-financial incentives:
1. Shortcut for international manufacturers to receive authorization for production and sales of pH1N1 vaccine in Japan.

Groups affected
National government and local governments, pharmaceutical manufacturers (domestic and international), specialists in infectious diseases (Expert Advisory Committee of Government), doctors, public

3. Characteristics of this policy

<table>
<thead>
<tr>
<th>Degree of Innovation</th>
<th>traditional</th>
<th>innovative</th>
</tr>
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<tbody>
<tr>
<td>Degree of Controversy</td>
<td>consensual</td>
<td>highly controversial</td>
</tr>
<tr>
<td>Structural or Systemic Impact</td>
<td>marginal</td>
<td>fundamental</td>
</tr>
<tr>
<td>Public Visibility</td>
<td>very low</td>
<td>very high</td>
</tr>
<tr>
<td>Transferability</td>
<td>strongly system-dependent</td>
<td>system-neutral</td>
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The process of forming pH1N1 vaccine policy was partly opended to the public and the media. However, frustration from infectious disease specialists and other physicians was expressed a lot through the media because disclosure of information regarding the imported pH1N1 vaccine was not sufficient and progress of forming pH1N1 vaccine policy was quite slow.

There is still a risk of a lawsuit against domestic vaccine manufacturers for death or health damages caused by pH1N1 vaccine. The Act on Special Measures concerning the Relief of Pandemic Influenza Vaccine-related Adverse Events provides tort liability immunity only to international vaccine manufacturers.
4. Political and economic background

During the process of forming and implementing the pandemic influenza policy, the Democratic Party of Japan (DPJ) won the Lower House Election in August 2009 and took office. As previously reported in (14)2009, the DPJ proclaimed more politician-led government rather than bureaucrat-administered one which made a shift of power for decision making and resulted in a strain on agreement amongst stakeholders.

Change of government

From the emergence of pH1N1 through September 2009, government run by Liberal Democratic Party formed and implemented pH1N1 vaccine policy. From September 2009, DPJ took over the policy.

5. Purpose and process analysis

Origins of health policy idea

In 2004, the Act on Prevention of Infectious Diseases and Medical Care for Patients Suffering Infectious Diseases was amended. This amendment stipulated the roles of central and local governments to respond to an epidemic of a new influenza. Following the publication of preparedness planning by the World Health Organization, in November 2005 the Japanese government issued the "Pandemic Influenza Preparedness Action Plan of the Japanese Government" which was revised three times and finalized in February 2009. This plan was supplemented with thirteen operational guidelines which include a vaccination plan.

After the emergence of pH1N1 in April 2009, the Office for Pandemic Influenza, chaired by the Prime Minister, was established in the Cabinet as the Action Plan projected. Based on the operational guideline of a vaccination plan, the office proclaimed to process production of pH1N1 vaccine urgently. The Expert Advisory Committee of Government, that supported the office with the point of view of specialists of infectious diseases, offered an opinion that production of pH1N1 vaccine should start as soon as it was ready, then production of seasonal influenza vaccine should be stopped. Following the opinion, the MHLW requested domestic vaccine manufactures to produce pH1N1 flu vaccine from mid-July 2009. At that time, import of pH1N1 vaccine was not publicly discussed yet, including whether the government had signed a purchase agreement for vaccines with vaccine manufacturers.

On the other hand, the Japanese government did not recommend pH1N1 vaccine for the public based on the Preventive Vaccination Act since pandemic influenza A(H1N1) had a lower case-fatality rate than expected and than avian influenza. The severity of pH1N1 was officially specified in the "Basic response policy to pandemic influenza" issued by the Office for Pandemic Influenza in the Cabinet on May 22, 2009. Therefore, pH1N1 vaccine was dispensed as a general human biological product and people in Japan would get vaccinated on a voluntary basis.

This specification of pH1N1 vaccine in the law raised an issue: how to compensate adverse events and deaths related to the vaccine. Since pH1N1 vaccine was dealt as a general human biological product, compensation for adverse events and death caused by pH1N1 vaccine would normally be paid through the "Adverse Drug Reaction Relief System", that is applied to health related injuries and deaths by human biological products in general, not through the "Relief System for Injury to Health with Vaccination" based on the Preventive Vaccination Act.

The budget of the "Adverse Drug Reaction Relief System" to compensate for deaths or health damages caused by appropriately used prescribed and purchased drugs is mostly funded by the contribution of pharmaceutical companies. The amount of the contribution depends on the amount of the production of the drugs which the companies plan to produce and sell. Therefore, vaccine manufactures of the pH1N1 vaccine were supposed to pay the contribution in the proportion to production of the vaccine. The contribution was supposed to be a financial burden
for vaccine manufacturers which would discourage them from the production and sale of pH1N1 vaccine in Japan.

Moreover, it was bad for patients as well. The amount of compensation under the "Adverse Drug Reaction Relief System" was substantially lower than the amount of compensation under the "Relief System for Injury to Health with Vaccination" based on the Preventive Vaccination Act. Therefore, another instrument was needed to fill the gap in the amount of compensation between these two systems, and that was the Act on Special Measures concerning the Relief of Pandemic Influenza Vaccine-related Adverse Events.

On October 1 2009, the Office for Pandemic Influenza in the Cabinet announced "the basic policy for pandemic influenza A(H1N1) vaccine" which stipulated processes to implement pH1N1 vaccine in local communities, priority groups, costs and compensation for death or health damages caused by pH1N1 vaccine.

**Initiators of idea/main actors**

- Government
- Providers
- Patients, Consumers
- Scientific Community
- Private Sector or Industry
- Political Parties

**Approach of idea**

The approach of the idea is described as: renewed: In the USA, the Public Readiness and Emergency Preparedness Act for H1N1 provides legal liability protections for vaccine manufacturers.

**Stakeholder positions**

The coalition government consisting of the DPJ, the Social Democratic Party and Kokumin Shinto (People’s New Party) supported the bills regarding Special Measures concerning the Relief of Pandemic Influenza Vaccine-related Adverse Events whereas the Liberal Democratic Party strongly opposed the bills for political reasons. They complained that no other political parties and the public were involved in the process of developing and passing the bills. When the bill passed, LDP members were absent from parliament in order to show their strong opposition to the bill. LDP did not oppose the contents of the bill though.

**Actors and positions**

Description of actors and their positions

**Government**
- Cabinet
- Ministry of Health, Labour and Welfare
- Ministry of Finance

- very supportive strongly opposed

**Providers**
- Doctors

- very supportive strongly opposed

**Patients, Consumers**
- Consumers

- very supportive strongly opposed

**Scientific Community**

-
Influences in policy making and legislation

In October 2009, the Bills regarding Special Measures concerning the Relief of Pandemic Influenza Vaccine-related Adverse Events were endorsed by the Cabinet. Although the LDP strongly opposed them, the Diet controlled by the DPJ passed the bills, which maintained almost original purposes and contents. The Act on Special Measures concerning the Relief of Pandemic Influenza Vaccine-related Adverse Events took effect immediately after the passage.

Legislative outcome
success

Actors and influence
Description of actors and their influence

Government
- Cabinet
- Ministry of Health, Labour and Welfare
- Ministry of Finance

Providers
- Doctors

Patients, Consumers
- Consumers

Scientific Community
- Expert Advisory Committee of Government

Private Sector or Industry
- Vaccine Manufacturers

Political Parties
- Democratic Party of Japan
- Liberal Democratic Party
- Social Democratic Party
- Kokumin Shinto (People’s New Party)

Positions and Influences at a glance
Adoption and implementation

The Japanese government had negotiated an agreement with international vaccine manufacturers to secure a sufficient amount of pH1N1 vaccine, complementing the production by domestic vaccine manufacturers, which was originally expected to cover the whole population who seeks to get vaccinated. On October 6, 2009, the Japanese government announced that two international vaccine manufactures, Novartis and GlaxoSmithKline (GSK), and the Japanese government reached an agreement to procure 9.9 million doses (2.5 million doses from Novartis, 7.4 million doses from GSK) of pH1N1 vaccine, that costed 112.6 billion yen.

The MHLW implemented a case-reporting system for patients who suffered adverse events from pH1N1 vaccine and formed a commission for reviewing the case and judging whether harms of the case were related to pH1N1 vaccine or not.

Monitoring and evaluation

The MHLW monitored the amount of dispensation of pH1N1 vaccine in each prefecture and regularly reported the results to the public and the media. The number of reported cases of adverse events and a report of the reviewing commission into the cases were also made public almost every month.

Review mechanisms

Mid-term review or evaluation

Dimensions of evaluation

Outcome

Results of evaluation

As of March 2010, the MHLW announced that 3,645 doses of imported pH1N1 vaccines were dispensed and 541
people got vaccinated with the imported vaccine, and that 3.9 million doses of domestic pH1N1 vaccines were dispensed. Overall, estimated 22.8 million doses of pH1N1 vaccines were used in Japan by March 28, 2010.

As of March 28, 2010, 2,422 cases of adverse events due to pH1N1 vaccine were reported, which included 415 critical cases and 133 deaths.

6. Expected outcome

Securement of a sufficient amount of pH1N1 vaccine was successful, but the inconsistency of the pH1N1 vaccine policy blurred the objectives of the policy, which resulted in a low vaccination rate and huge stocks of pH1N1 vaccine in hospitals and clinics.

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<th>marginal</th>
<th>fundamental</th>
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<td>Level of Equity</td>
<td>system less equitable</td>
<td>system more equitable</td>
</tr>
<tr>
<td>Cost Efficiency</td>
<td>very low</td>
<td>very high</td>
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The vaccination rate of pH1N1 was not very high; estimated at around 17% by the end of March 2010. The cost of pH1N1 vaccine might be one of the reasons for the low acceptance rate in Japan. The cost was shifted to people who want to get vaccinated because of the decision that the Japanese government did not recommend the pH1N1 vaccine for the public based on the Preventive Vaccination Act since pandemic influenza A(H1N1) had a lower case-fatality rate than expected and than the avian influenza. The national price was 3,600 yen per shot.

Delayed timing of dispensation of pH1N1 vaccine might be another reason. Authorization of imported pH1N1 vaccine was issued two months after the peak of incidence of patients with pH1N1 in Japan. The mismatch between the needs of the public and timing of dispensing pH1N1 vaccine might result in a large stock in hospitals and clinics.

In August 2010, in response to condemnation from hospitals and clinics about overdispensation by the government, the Japanese government announced re-procurement of pH1N1 vaccine which was overdispensed and stocked in hospitals and clinics.

7. References

Sources of Information

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