European Federation of Pharmaceutical Industries and Associations

6th July, 2016

To the media

EFPIA's Statement on Secure Supply of Vaccines

European Federation of Pharmaceutical Industries and Associations (EFPIA Japan)
Vaccine Sub-committee

European Federation of Pharmaceutical Industries and Associations (EFPIA Japan, Chairman Carsten Brunn) Vaccine Sub-committee (Chair Jun Honda) has long been making proposals on the future directions of Japanese vaccine business.

We hereby present EFPIA Japan's position (statement) on securing stable supply of vaccines, coinciding with July 6th "Vaccine Day"*. EFPIA Japan and the member companies are committed to efforts and assistance to the Japanese authorities in order to contribute to Japanese public health

*The day when first modern vaccine was used on a human subject by Louis Pasteur

Contacts:
EFPIA Japan Public Relations Committee:
S. Honda (03-5786-5041), C. Saeki (03-6301-4147)
EFPIA Japan Secretariat
N. Saito (03-6301-3066)
EFPIA Japan Vaccine Sub-committee
J. Honda (03-5786-5159)

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EFPIA Japan's Statement on Securing Stable Supply of Vaccines

1. **Vaccines manufacturing operations are complex and lengthy, and thus increasing capacity in a short time frame is not feasible. EFPIA Japan believes that the stable supply system anticipating the crisis situation needs to be established, and that measures should be taken to minimize risk and impact of the crisis situation, before the crisis.**

   In the recent incidents related to GMP violation and earthquake disasters, it has come as a reminder that vaccines with limited supply source(s), cannot secure alternative supply source(s) and that even if they were secured, the production time required would be in the order of several months.

   Therefore, for important vaccines like those in the NIP, we believe that by diversifying supply sources to domestic and global sources (i.e. multiple manufacturers) to co-exist, it would allow secure stable supply in Japan. Many of the foreign manufacturers are global manufacturers, and we can maximize the following advantages:

   - Robust systems and processes with large manufacturing scale and inventory volume
   - Geographically diversified network providing flexibility in ensuring sustainable long-term supply even in the event of a crisis situation
   - Meet regulatory standards of major regulatory authorities such as FDA, EU and WHO

   For non-routine or specialty vaccines, we believe long term supply purchase agreements and stockpiling are valuable means worthy of investigation.

2. **Currently, there are differences in the manufacturing and release times between domestic and import vaccines due to differences in regulatory requirements between the two. This is a major burden on early introduction of vaccines from outside Japan and on release of vaccines into the Japanese market. EFPIA Japan believes that it is necessary to promote harmonization of regulatory requirements and to alleviate above burden in order to minimize stable supply risk.**

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It would require a lengthy period of more or less 6 months for vaccines to be released into the market after filling/formulation by the manufacturers. During this time, quality testing and summary lot protocol review will be conducted, but by revisiting this process, e.g. by simplifying release processes (redundant quality tests and national tests) or conducting them in parallel, it may become possible to accelerate without compromising product quality.

By harmonizing quality requirements with those outside Japan, we believe that it would lead to faster introduction of new vaccines, and contribute to secure supply.

Collaboration between the government and the manufacturers would be indispensable during crisis management. EFPIA Japan and the member companies are committed to efforts and assistance to the Japanese authorities in order to realize more stable vaccines supply and to contribute to Japanese public health

Ends