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Secretary General
IPEC Japan

* IPEC Japan Update
*I wish to express my gratitude to the good will sent to the Tohoku and Kanto earthquake.
The Japanese Pharmacopoeia 16th Edition was promulgated in March 24, 2011.

Number of Articles:

- Totaling 1764, Adding 106, Deleting 15

Novel pharmaceutical excipients articles:

- Trehalose Hydrated

Revised test method in General Tests: 15

1. Liquid Chromatography
2. Residual solvent Test
3. Conductivity Measurement
4. pH Determination
5. X-ray Powder Diffraction Method

etc...

**IPEC Japan cooperated with JP.**
Completion of the work to make revised version of the book “Guidebook to Implementing the Self-imposed Standards of GMP for Pharmaceutical Excipients” and Holding a Explanation Meeting

* IPEC Japan Update
Revision of the Compendium “Japanese Pharmaceutical Excipients (JPE)”

The last revision of the JPE was made in 2003 and successively its supplement was published in 2006. The authority concerned have accepted to make revision this time and now its work is on the way assuming to terminate by the end of this fiscal year. IPEC Japan is arranging documents to be submitted to the Committee of JPE.
IPEC Japan Pharmaceutical Excipient Seminar
Pharmaceutical Excipient Seminar is held every year regularly.
The 10th Seminar was held as follows;

Tokyo: February 2, 2011
Osaka: January 31, 2011

* IPEC Japan Update
Outline

◎ There was a large earthquake off the coast of Sanriku district at about 14:46 on Mar. 11, 2011. The quake was M. 9.0. on Richter scale. At some coast, a massive tsunami of 23 m was observed. Then, Tokyo had 5°+ degrees of a Japanese seismic intensity. Fortunately, the damage was comparatively small.

◎ The tsunami did damage to the Fukushima Dai-ichi Nuclear Power Station. It was so powerful that plants were destroyed. Parts of their core pellets were melted, and the houses of the plants were blown away by hydrogen explosions. They are now out of control in spite of strenuous work. Radioactive substances were discharged into air. The condition was assessed at INES (International Nuclear Event Scale) 7.
Regulation of Food and Pharmaceutical in Japan

• Food

Safe security of food – By “Food Sanitation Act”

Quality control – HACCP

(Hazard Analysis and Critical Control Point)

• Pharmaceutical

Safe security of pharmaceutical – By “Pharmaceutical Affairs Act”

Quality control – GMP (Good Manufacturing Practice)
## Temporary Radiation Limit of Foods in Japan

<table>
<thead>
<tr>
<th>Kind of radioactive substance</th>
<th>Limit value settled by the Ministry (MHLW) Bq/Kg</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Radioactive Iodine</strong>&lt;br&gt;(Half-life: 9 days)</td>
<td><strong>Drinking water</strong>&lt;br&gt;300&lt;br&gt;<strong>Milk • Dairy products</strong>&lt;br&gt;100 (Infant)&lt;br&gt;<strong>Vegetables (except root vegetables &amp; potatoes)</strong>&lt;br&gt;2000&lt;br&gt;&lt;br&gt;<strong>Fishes</strong></td>
</tr>
<tr>
<td><strong>Radioactive Cesium</strong>&lt;br&gt;(Half-life: 30 years)</td>
<td><strong>Drinking water</strong>&lt;br&gt;200&lt;br&gt;<strong>Milk/Dairy products</strong>&lt;br&gt;&lt;br&gt;<strong>Vegetables</strong>&lt;br&gt;500&lt;br&gt;<strong>Cereals</strong>&lt;br&gt;<strong>Meat, Egg, Fish, etc.</strong></td>
</tr>
</tbody>
</table>

## Health Influence

- **1000 mSv**—Appearance of vomiting symptom
- **500 mSv**—Decrease of lymphocyte occurrence
- **50 mSv**—Exposure limit of worker at nuclear power plant, etc.
- **1 mSv**—Annual exposure limit for general person
- **0.19 mSv**—Round trip between Tokyo and NY by airplane
- **0.05 mSv**—X-ray exposure at mass-screening of breast
Cumulative amount of radiation in the circumstance of Fukushima Dai-ichi Nuclear Power Station (Apr. 28)

<table>
<thead>
<tr>
<th>Location</th>
<th>Radiation</th>
<th>Measured hour</th>
<th>Average amount: mSv/hour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fukushima-pref.</td>
<td>0.811</td>
<td>785 hrs</td>
<td>0.0005</td>
</tr>
<tr>
<td>Minami-soma-shi</td>
<td>0.677</td>
<td>840 hrs</td>
<td>0.0006</td>
</tr>
<tr>
<td>lidate-mura</td>
<td>13.070</td>
<td>837 hrs</td>
<td>0.0096</td>
</tr>
<tr>
<td>Namie-cho</td>
<td>22.850</td>
<td>813 hrs</td>
<td>0.0173</td>
</tr>
<tr>
<td>Namie-cho</td>
<td>9.958</td>
<td>814 hrs</td>
<td>0.0073</td>
</tr>
</tbody>
</table>

Caution zone
Set by considering the cumulative amount, etc.

Unit: mSv (millisievert)

Revised from Mainichi newspaper (Apr. 30)
Besides Sympathy and solidarity, supports and donations were presented from all over the world.

The emergency assistance teams and medical relief teams from 20 countries and regions. --- Experts from UNOCHA (UN Office for the Coordination of Humanitarian Affairs), IAEA (International Atomic Energy Agency), and WFP (World Food Programme), etc.

Many pharmaceutical companies in Japan offered medicines and made a contribution of money, too.
Calming down of the nuclear reactor
In spite of strenuous measures, new problems happen in sequence.

Shortage of electricity
Due to the nuclear accidents, TEPCO (Tokyo Electric Power Company) is anxious about the power shortage. Not only corporate offices but also homes and factories must save the power. The shortage of this summer is estimated to be several hundred kilowatts (15 to 25% down).

Shortage of finance
It is said that financial dispatch approximately 20 billion yen ($0.24 billion) is required for the reconstruction.

The following plans are under discussion.
1) Increase of the consumption tax rate
2) Issue of government bonds
First of all, I would like to express my gratitude for all of the support from the governments and people of numerous countries in the wake of the earthquake and tsunami that struck the Tohoku region of Japan's Honshu Island on the 11th of March, 2011, and the nuclear plant accident that occurred in the immediate aftermath.

The five prefectures in the northeast part of the country were affected the most by the earthquake and tsunami. Over 30,000 lives are feared to have been lost, and as many as 400,000 people have fallen victim to the disaster.
These five prefectures have a combined population of approximately ten million (about 7.7% of the total population of Japan) and area of about 52,000 square kilometers (about 13.7% of the total land area of Japan); an area of about 4,000 square kilometers is considered to have been directly affected by the earthquake and tsunami.

Tireless restoration efforts are being made to recover from the damage done by these disastrous events, and although it is a time-consuming process, I believe that new towns will emerge in due time.

What is more problematic is the troubled Fukushima nuclear power plant. The potential consequences of this accident do pose a serious concern to us.

It is our understanding that this is no more than a matter limited to the nuclear plant and the area within a 30-km radius of the site; the situation in the Tokyo area, which is 200-300 km away from Fukushima, for instance, is that life is perfectly normal with the exception of some impact due to power shortages.
IPEC Japan showed the fundamental viewpoint to the members of the council (May 2 of this year). The thoughts on the safety of pharmaceutical excipients in relation to radioactivity is summarized as followed:

1) As pharmaceuticals are used on the limited purpose, the regular intake is very small compared to that of food or water. Therefore, the health influence is extremely small.
2) Water for pharmaceutical excipients’ production has a quality that is judged to be suitable for safe drinking or a similar quality to that. Therefore, the pollution risk with water is extremely small.
3) Manufacturing processes of pharmaceutical excipients are performed under the strict control such as GMP control and other regulations. Therefore, the pollution risk in the process is extremely low.
4) Pharmaceutical excipients are produced and stored outside of the evacuation area that is instructed or controlled by the administration. Therefore, the pollution possibility is extremely.

Basic thoughts of FPMAJ* was expressed as a message on April 21, 2011.
“There is no issue of radiation contamination in pharmaceutical products which have been produced in Japan and distributed domestically or exported overseas.”  
*The Federation of Pharmaceutical Manufacturers’ Associations of Japan
The view was shown as followed: Raw materials of pharmaceuticals (including medicine manufacture water) and the finished products are generally recognized as safe because their qualities (including radioactivity) are controlled by the standards of water service and the food.

IPEC Japan stands at the same position as FPMAJ, MHLW as well as Japan Cosmetic Industry Association, Japan Food Additives Association.