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PMDA Updates

April, 2013

News

1. PMDA provides training program to Indonesian officials (March 11 to 15)

PMDA accepted three officials from the National Agency of Drug and Food Control (NADFC), Republic of Indonesia, from March 11 to 15, 2013 and provided them with a one-week training program on regulatory review of drug applications. During the program, the Japanese review system and the basic principles thereof were explained by PMDA reviewers engaged in the evaluation of new drugs, biological products or generic drugs. In the lectures, lively discussions were held, which enhanced mutual understanding between PMDA staff members and NADFC trainees.

2. Medical Device Roundtable and Medical Device Regulatory Symposium (March 15 and 16)

Two members of PMDA's Office of International Programs participated in the Medical Device Roundtable and the Medical Device Regulatory Symposium hosted by the Health Sciences Authority of Singapore (HSA). In Medical Device Roundtable (March 15), representatives from the regulatory agencies of Japan (PMDA), US, Australia, UK and Singapore, and those from academia and industry presented the current status of registries of orthopedic and cardiovascular devices in each country. Vigorous Roundtable discussions ensued on the goals and approaches for device registries in Singapore, with the participation of the speakers who are leading experts in post-marketing registries. In the Medical Device Regulatory Symposium (March 16), intended mainly for Singaporean industry representatives, the information on medical device regulation in each country was updated by regulators from Japan, Australia, UK and Singapore, with Q&A afterwards.

3. The third Science Committee held (March 18)

At the third Science Committee meeting which was held on March 18, the performance for FY 2012 and planned activities for FY 2013 of the Science Committee and the Subcommittees were reported. Moreover, future administrative rules of the Science Board (for both Science Committee and Subcommittees) were confirmed, including rules for working groups and procedures to invite external experts to the meetings.

For more information, please click here.

4. The third PMDA Advisory Council Meeting of FY 2012 held (March 18)

PMDA's Advisory Council, which consists of external qualified members from a variety of fields, had its third meeting for FY 2012. In the meeting, PMDA presented outlines of its operating plan and budget for FY 2013. The plan addresses efforts for strengthening the consultations and review system to facilitate market introduction of new drugs and medical devices originated in Japan, enhancing cooperative relationship with regulatory agencies in Asian countries, advancing safety measures utilizing the medical information database, and actively providing information, such as English translations of review reports, to the international community.

5. PMDA participates in the third IMDRF meeting (March 19 to 21)

Dr. Atsushi Tamura, International Liaison Officer for Medical Devices of PMDA, participated in the 3rd meeting of International Medical Device Regulators Forum (IMDRF) held in Nice, France, as the member of the Management Committee. The first and final days of the Forum were dedicated to closed-session meetings for regulators. On the second day, in the open forum session organized to involve various stakeholders, the status of ongoing WG activities was reported and the stakeholders' opinions were shared. China has formally joined the Management Committee for the first time, making a total of seven member economies and countries of the Commitee (i.e., Japan, US, EU, Australia, Canada, Brazil and China).

The next Forum is scheduled for November 2013 in Belgium.

Safety Information

Pharmaceuticals and Medical Devices Safety Information No.300, March 27, 2013

1. Implementation of the "Risk Management Plan"
2. Revision of Precautions (No. 244)
3. List of Products Subject to Early Post-marketing Phase Vigilance (as of March 2013)

http://www.pmda.go.jp/english/service/precautions_2012.html

English translations of review reports

The followings are current information about English version of review reports on PMDA web site.

Pharmaceuticals http://www.pmda.go.jp/english/service/drugs.html

Name	Active Ingredient	Posting date
Quattrovac	adsorbed diphtheria-purified pertussis-tetanus-inactivated polio (Sabin strain) combined vaccine	March 29
Tetrabik	adsorbed diphtheria-purified pertussis-tetanus-inactivated polio (Sabin strain) combined vaccine	March 29

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
April 26	ICH E11 Guidelines Workshop	Beijing, China
May 21-25	IMDRF RPS WG	Washington D.C., U.S.
May 23-24	IGDRP	Canberra, Australia
June 1-6	ICH meeting	Brussels, Belgium
June 23-27	DIA 2013 49th Annual Meeting	Boston, U.S.

Letters from the liaison officers

Our liaison officers deliver lively reports for their activities at their stationed overseas authorities.

EMA public consultation on 'Concept paper on the need for a reflection paper on quality aspects of medicines for older people' was started on 5th April.

There is no specific legal requirement for the development of medicines for geriatric use, unlike the paediatrics . Geriatrics is one of the major population which take medicinal products. Nevertheless, there may not be robust evidence of efficacy and safety and appropriate package/form formulation for older population. Given the growing older population, it should ensure that the specific needs of the elderly are integrated during the development, approval and use of medicines. EMA already established Website of 'Medicines for Older People' as one of special topics and has organised several workshops and published guidances .

The agency is planning to publish a reflection paper for older people from quality aspect, as it is described within the title. This project will proceed accompanying with existing Geriatric Expert Group. PMDA also started to analyse circumstance of assessment of geriatric data to for robust evidence of safety and efficacy in the population. Elderly is growing population in both EU and Japan. As a Liaison official, I would like to support both agencies will collaborate to advance the project efficiently for more appropriate use of medicinal products for geriatrics.

1) Concept paper on the need for a reflection paper on quality aspects of medicines for older people
http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=WC500141560&murl=menus/document_library/document_library.jsp&mid=0b01ac058009a3dc

2) REGULATION (EC) No 1901/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:378:0001:0019:en:PDF

3) Medicines for Older Peoples
http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000249.jsp&mid=WC0b01ac058004cbb9

Dr. Junko Sato
PMDA's International Liaison Officers stationed at EMA in the United Kingdom

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Microbiological Control of Compendial Articles; a workshop on current status and future directions of compendial standards was held on March 18-19 at USP. The workshop presented information on microbiological control including sterility assurance, properties and the limits of tests, related FDA guidance, current discussion in USP, JP and EP in the area. Comments on actual condition of product manufacturing in pharmaceutical industry, development of new test methods, future directions of the standards were also presented, and vigorous discussion took place. Among those, there was an argument that rapid/modern microbiological test methods are very much needed for biological product, such as cellular and tissue-based products, and their international harmonization will be desirable.

Establishment of internationally harmonized standards for test methods for products of new field like cellular and tissue-based products would facilitate the development of innovative products in the area. It may take time, but I hope to be able to contribute to these activities.

Dr. Eriko Fukuda
PMDA's International Liaison Officers stationed at USP in the United States

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