Japan Pharmaceutical Manufacturers Association
Nihonbashi Life Science Bldg., 2-3-11, Nihonbashi-Honcho, Chuo-ku, Tokyo, 103-0023 Japan
TEL: 81-3-3241-0374 FAX: 81-3-3242-1767

April 11, 2018

News Release

"The 7th Asia Partnership Conference of Pharmaceutical Associations (APAC)"

The 7th **A**sia **Pa**rtnership **C**onference of Pharmaceutical Associations (APAC) was held on April 10th, 2018 in order to realize our mission; "to expedite the launch of innovative medicines for the peoples in Asia". Not only pharmaceutical industries but also health authorities and academia from Asia including Japan participated in this conference.

In this year's conference, active discussions and policy proposals were conducted at the three sessions: 1) Regulations and Approvals (RA) Session, 2) Access to Innovative Medicines (ATIM) Session, 3) Drug Discovery Alliance (DA) Session. We are pleased to let you know this year's agreement reached at each session, as per the attached document.

Based on this agreement, JPMA would like to strive for resolution of various issues in collaboration with pharmaceutical associations, governments, authorities and academia in Asia.

END

Contact: Public Relations Department, JPMA
Phone: +81-3-3241-0374

Japan Pharmaceutical Manufacturers Association
Nihonbashi Life Science Bldg., 2-3-11, Nihonbashi-Honcho, Chuo-ku, Tokyo, 103-0023 Japan
TEL: 81-3-3241-0374 FAX: 81-3-3242-1767

Attachment: Consensus of 7th APAC

Regulations and Approvals；RA

Good Registration Management (GRM)

- RA-EWG will continuously contribute the implementation of the APEC GRM CoE Workshop and the GRM/GSubP trainings in collaboration with GRM CoE.
- In FY2018, RA-EWG starts the examination of performance indicators for GRM/GSubP to assess the impact of the activities.

Conditional Early Approval (CEA) System

- In the 7th APAC meeting, we have reached a consensus that CEA is an effective and efficient way to promote early access to highly necessary medicines for patients in Asia, and that multi-regional drug development and entry of medicines to different countries may face challenges without convergence of CEA approaches.
- RA-EWG will continue exploring the possibility of further convergence of early approval systems in Asia.

Access To Innovative Medicine；ATIM

Site Master File (SMF)

- Regulators and Industries have reviewed the SMF template, and reached consensus to use it.
  (SMF template will be informed & discussed in PIC/s
  Committee Meeting in Geneva as regional initiative actions.)

Post-approval Variations

- In the 7th APAC meeting, we have confirmed each difference for the Post-approval Variations fields, especially for CMC & Stability documents
- APAC will seek a possibility of convergence of the framework to facilitate the management of post-approval changes in a predictable and efficient manner.

Japan Pharmaceutical Manufacturers Association
Nihonbashi Life Science Bldg., 2-3-11, Nihonbashi-Honcho, Chuo-ku, Tokyo, 103-0023 Japan
TEL: 81-3-3241-0374 FAX: 81-3-3242-1767

Attachment: Consensus of 7th APAC

Drug Discovery Alliances；DA

- Pillar 5 has made remarkable progress in creation of the cross-border open innovation platform using natural products. APAC DA-EWG commits to advancing Pillar 5 as an effective initiative to realize "Drug Discovery Ecosystem in Asia"
- "Drug Discovery Ecosystem in Asia" is a foundation of productive cross-border open innovation. Establishment of the system will create more synergy among the stakeholders and increase chances of innovation in drug discovery.
- Networking, communication, information sharing and capacity building are critical to establish "Drug Discovery Ecosystem". APAC DA-EWG will promote them by working on the Pillar activities in collaboration with Asian countries.