APAC
Asia Partnership Conference of Pharmaceutical Associations

27 July 2020

Mr. Frank Chan, Drug Office, Department of Health, Hong Kong SAR

Dr. Hasenah Ali, Director of National Pharmaceutical Regulatory Agency, Ministry of Health Malaysia

Dr. Ir. Penny K Lukito, MCP, Head of BPOM, Indonesia

Minister Jiao Hong, Commissioner of China's National Medical Products Administration (NMPA)

Minister Lee Eui-Kyung, Ministry of Food and Drug Safety, South Korea

Dr. Mimi May Ling Choong, Chief Executive Officer of Health Sciences Authority, Singapore

Dr. Paisarn Dunkum, Secretary General, Food and Drug Administration, Thailand

Dr. Rolando Enrique D. Domingo, Director General of Food and Drug Administration, the Philippines

Dr. Shou-Mei Wu, Director General, Taiwan Food and Drug Administration

Mr. Vu Tuan Cuong, Director General, Drug Administration of Vietnam

Dr. Yasuhiro Fujiwara, Chief Executive, Pharmaceuticals and Medical Devices Agency, Japan

Dear Mr. Frank Chan, Dr. Hasenah Ali, Dr. Ir. Penny Lukito, Minister Jiao Hong, Minister Lee Eui-Kyung, Dr. Mimi Choong, Dr. Paisarn Dunkum, Dr. Rolando Domingo, Dr. Shou-Mei Wu, DAV Director General Vu Tuan Cuong and Dr. Yasuhiro Fujiwara,

We, the representatives of the R&D-based pharmaceutical industry appreciate the development of guidance to facilitate the availability of medicines in the midst of COVID-19, and we would like to emphasize the critical need for health authority to maintain regulatory flexibility and consider new normal ways of working moving forward.

We recognize the ongoing COVID-19 pandemic poses challenges to our National Regulatory Agencies (NRAs). We seek to work in partnership with you to ensure the continuity of supply of medicines and treatment to patients remain feasible when "normal" production and operations are also impacted by the pandemic. Specifically, we believe there are four important best practices surrounding regulatory flexibility that we can work through collectively for areas in need:

Collaborative, coordinated scientific assessment leveraging on reliance practices

In the context of public health emergencies, reduced personnel will result in reduced work capacity for both NRAs and pharmaceutical companies. A key consideration in tackling this issue is to have in place regulatory reliance mechanisms, whereby NRAs take into account and give significant weight to evaluations performed by another stringent RA. Regional reliance such as the ASEAN Joint Assessment (AJA) will increase efficiency without duplication in efforts. We therefore strongly recommend regulatory reliance or workshare mechanisms such as AJA, to be applicable to all disease areas, all product types and all submission applications including line and indication extensions and post-approval changes.

Furthermore, as the inability to travel may impede some regulatory processes such as onsite inspections. Sharing of one's on-site inspection or document audit records and other regulatory information on the assessment of the manufacturing site will aid to inform another NRA on the regulatory decision-making. With the approval issued by reference RAs, NRA can leverage on the outcome to waive off site inspection and/or registration procedures. Similarly, using risk-based approaches NRAs can take account of the work already done by other reference RAs and reduce import testing. These reliance mechanisms will help manage resource capacity issues whilst simultaneously accelerating access to medicines and vaccines.

Enhanced use of digital platform for communication

Physical visits to the office are often required for some NRAs as part of the regulatory processes. Optimizing the use of digital tools for communication - as simple as enhancing the use of emails for receiving documentation, sending notices to applicant electronically, or allowing for certification through emails - could have a significant impact. We therefore strongly recommend having procedures in place for using online platforms in processing activities from approval to life-cycle management including licenses renewals.

Furthermore, in order to enhance efficiency in work sharing and information access across different NRAs, it might be recommended to consider and establish sustainable digital platform by which all the involved NRAs can share information such as assessment report, labeling, core approved data, marketing authorization, etc., for future multi-national collaboration to reduce drug lag.

Acceptance of electronic document

Promoting and facilitating the acceptance of electronic documents (e.g. eCPP, eGMP), waiving of the need for a wet ink signed original/ physical copy and legalization requirements is key in ensuring continuity of regulatory processes. We are encouraged that NRAs in general are receptive towards the acceptance of electronic document during the pandemic.

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Moreover, it has come to our attention that several NRAs have adopted positive approaches in adopting electronic documents as the new normal. We therefore propose for all NRAs to consider adopting the same approach in accepting electronic document as a long-term approach in line with the evolution of regulatory landscape into digitization.

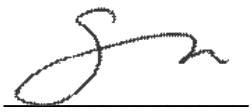
Integrate and streamline regulatory processes

Integrate, where feasible, the assessment and IT system collected at various stages such as pre-marketing evaluation, inspection, post approval change, PSUR, risk management plan, laboratory testing, etc., to minimize duplication by asking for documents previously evaluated by one department to be compiled again at the point of submission to another department. Streamlining of remote desktop reviews to fulfill the legal requirement for inspections (i.e. existing practical guidance/best practices provided by PIC/S); 'grace periods' for both post approval change implementation and license renewals, and practice multi-sites in one license for marketing authorization are essential to ameliorate the impact of the ongoing pandemic on availability of medicines and vaccines.

We are committed to working together with NRAs in Asia towards identifying best regulatory practices and fostering international alignment, while facilitating constructive dialogue with the R&D-based pharmaceutical industry. We hope that the above four areas proposed can be considered a pragmatic approach to enable efficient processes and system.

We look forward to hearing your response and welcome any virtual meeting for further discussion.

Best regards,



George Nakayama

President, JPMA

On behalf of

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Abbreviation:

APAC	Asia Partnership Conference of Pharmaceutical Associations
BPOM	Badan Pengawas Obat dan Makanan (Indonesia FDA)
HKAPI	Hong Kong Association of the Pharmaceutical Industry
IPMG	International Pharmaceutical Manufacturers Group
IRPMA	International Research-Based Pharmaceutical Manufacturers Association
JPMA	Japan Pharmaceutical Manufacturers Association
KPBMA	Korean Pharmaceutical and Bio-Pharma Manufacturers Association
KRPIA	Korean Research-based Pharma Industry Association
PHAMA	Pharmaceutical Association of Malaysia
PHAP	Pharmaceutical & Healthcare Association Of The Philippines
PHIRDA	China Pharmaceutical Innovation and Research Development Association
PG	Pharma Group Vietnam
PreMA	Pharmaceutical Research & Manufactures Association
RDPAC	R&D-based Pharmaceutical Association Committee
SAPI	Singapore Association of Pharmaceutical Industries