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件名：	RE: Industry Supports for Covid-19 regulatory response
日付：	2020年8月10日 15:58:06

Dear President George Nakayama,

Thank you for your letter on 27 July 2020.

I am glad to receive the four practices APAC raised to enhance cooperation during the COVID-19 pandemic. As regards the four practices, first of all, I would like to briefly share what TFDA has achieved, by engaging with pharmaceutical industry.

- Regarding the issue of practice of reliance, TFDA has implemented several procedures to accelerate access to medicines and vaccines. The procedures include abbreviated review process for an application for new chemical entities and for drug master file with CEP/COS, as well as the fast track review process for an application for IND.
- Regarding the issues of digital platform for communication and electronic document acceptance, TFDA has built up eSubmission system that allows applications for IND and marketing authorization to be submitted electronically. Meanwhile, eCTD system complying with the ICH M8 guideline has been under construction.
- Regarding the issue of regulatory process and IT system, we have been working on the integration of different systems to reduce duplication of work.

Overcoming the spread of the pandemic is at the top priority and the most important goal for all of us at the moment. I believe that cooperation and collaboration are the keys to fighting against COVID-19. TFDA will continue to be open-minded and remain alert to all views and ideas.

Best Regards,

Shou-Mei Wu

Director General
Taiwan Food and Drug Administration
Ministry of Health and Welfare, Taiwan

寄件者: APAC管理者 <info@apac-asia.sakura.ne.jp>

寄件日期: 2020年7月30日 上午 11:44
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主旨: Industry Supports for Covid-19 regulatory response

Dear Dr. Shou-Mei Wu,

On behalf of RA-EWG (Regulatory Affairs – Expert Working Group) in APAC (Asia Partnership Conference of Pharmaceutical Association), we would like to commend your regulatory authority to coordinate regulatory responses and enhance cooperation during the COVID-19 pandemic.
This is a much-needed activity to ensure that globally we have the medicines and vaccines needed to fight against the pandemic.

Please find attached a letter outlining several areas where enhanced regulatory coordination and cooperation is seen as critical from our perspective.
We would like to take this opportunity to highlight our support and also our willingness to engage on these important topics.

If there are topics that we can co-develop at this most critical time then we are ready to call upon our experts from across industry to work with you.

Best regards,
APAC RA-EWG secretariat