Life Sciences Innovation Forum

Webinar Series on Financing Immunization Programs:
"Building the Right Regulatory Environment for COVID-19 Response & Long-Term Health Resilience"
7 July 2021

On 7 July, the APEC Life Sciences Innovation Forum (LSIF) hosted a webinar entitled **Building the Right Regulatory Environment for COVID-19 Response & Long-Term Health Resilience**; the fourth in the series, **The Role of Vaccination in Maintaining Health and the Economy During Pandemics.** This webinar brought together two expert presenters, **Prof. John Lim of Duke-NUS** and **Dr. Yi-Chu (Judy) Lin of the Taiwan Food and Drug Administration (TFDA)**, to consider regulatory agility, the expedited approach to emergency use authorizations during COVID-19, and the future of building health system resilience after COVID-19.

Regulatory Agility and Expedited Approach in Emergency Use

Dr. Yi-Chu (Judy) Lin reviewed the current status of the pandemic, then analyzed the actions taken by her economy against COVID-19 and the challenges presented by emergency use of vaccines. She lastly looked at the lessons learned from the present crisis. Lin explained how, as extraordinary measures have been required to shorten the vaccine development period during the current crisis, the regulatory framework for emergency action has responded accordingly. She listed key elements of Chinese Taipei's regulatory framework for emergencies (including the Pharmaceutical Affairs Act, Communicable Disease Control Act, and the Regulations for Approval of Specific Medical Products' Manufacturing or Importing), which have allowed the TFDA to accelerate review and approval of vaccines. Within 1.5 years, 17 vaccines have been developed and become available for use, 103 vaccines are undergoing clinical trials, and 184 vaccines are in pre-clinical development. Lin described how one of the most significant updates in regulation as a result of the pandemic is the rise in public-private partnership, and also highlighted the increase in international cooperation and global conversations due to COVID-19. The future of vaccine approval, Lin predicts, will change due to the building up of bilateral relationships.

During the Q&A, Dr. Lin flagged three key issues necessary for regulators to address moving forward:

- Regulatory frameworks for emergency use authorizations are crucial because they enable regulatory authorities to respond to the pandemic quickly
- Legal strategies such as ruling review or provider consultation will advance innovative development
- Financial support is crucial – especially sustainable financial support from governments or other organizations

Regulatory Agility During and After COVID-19

Prof. Lim reviewed how regulators have been responding to the pandemic, but emphasized that further changes are needed to adjust the way that we handle pandemics through the global health system in the future. In particular, Lim honed in on the role of regulatory agility as a necessary part of the COVID and post-COVID regulatory landscape. Echoing Dr. Lin, he recognizes that much has changed in the regulatory landscape during COVID-19, largely due to regulatory coordination and information exchange, and the use of reliance, referencing, and convergence. Regular virtual meetings by WHO, ICMRA, regional regulatory groupings and NRAs have taken place, and his hope is that such convenings become part of the 'new normal.'

Both speakers also addressed data and its role during the pandemic and broadly for improving the regulatory environment. Dr. Lin noted that data is immediately critical because of the need to address vaccine adverse events, the need to understand how to deal with variants and the need to understand how new vaccines are being developed. Prof. Lim called for more standardization of data among health systems, and more discussion on the curating of real-world data. This in particular may be an important area where a forum like APEC can make a difference.

Life Sciences Innovation Forum

To view a recording of the webinar and associated presentation slides, please visit the event page.
To participate in future webinars, please register online and you will be notified of future sessions.

Further Reading

https://www.duke-nus.edu.sg/core/think-tank/core-regulatory-perspective/making-sense-of-emergency-use-authorisations-(euas)-for-covid-19-vaccines-and-considerations-for-the-road-ahead

https://www.duke-nus.edu.sg/core/think-tank/core-regulatory-perspective/regulatory-agility-and-global-coordination-to-meet-the-challenge-of-covid-19-variants-preparing-for-the-next-generation-vaccines

<table>
<tr><th colspan="2">Meeting Agenda</th></tr>
<tr><td colspan="2">Opening remarks and welcome</td></tr>
<tr><td rowspan="2">Presentations</td><td>“Building the Right Regulatory Environment for COVID-19 Response & Long-Term Health Resilience”

• Moderator: Prof. John Lim, Executive Director, Centre of Regulatory Excellence (CoRE), Duke-NUS Medical School

<u>Speakers:</u>
• Dr. Yi-Chu (Judy) Lin, Senior Specialist, Taiwan Food and Drug Administration (TFDA), Ministry of Health and Welfare
• Dr. Fiona Frappier, Manager at the Office of Policy and International Collaboration, Biologics and Radiopharmaceutical Drugs Directorate, Health Canada</td></tr>
<tr><td><u>Key Questions:</u>
• How has the regulatory landscape changed in the past year, due to the exigencies and rapid adjustments stemming from the crisis? What steps have APEC economies taken to ensure that regulatory frameworks enable effective response to COVID-19? What reforms are still needed?
• With multiple “next generation” vaccines on the horizon (e.g. RNA and DNA-based vaccines, and vaccines employing new manufacturing methods), what are the regulatory frameworks and policies that can accelerate development, review, and approval of these vaccines?</td></tr>
<tr><td colspan="2">Moderated Discussion</td></tr>
<tr><td colspan="2">Audience Question and Answer Session</td></tr>
<tr><td colspan="2">Closing Remarks</td></tr>
</table>

Life Sciences Innovation Forum

Speaker Biographies

Professor John Lim

Professor John CW Lim is founding Executive Director of the Centre of Regulatory Excellence (CoRE) at the Duke-National University of Singapore Medical School (Duke-NUS), inaugural Chairman of the Consortium for Clinical Research & Innovation Singapore (CRIS), Senior Advisor at Singapore's Ministry of Health (MOH), and Policy Core Lead at the SingHealth Duke-NUS Global Health Institute (SDGHI). He is Professor of Practice at Duke-NUS and the NUS Saw Swee Hock School of Public Health. Formerly Chief Executive Officer of Singapore's Health Sciences Authority and Deputy Director of Medical Services (Industry & Research Matters) in MOH, Professor Lim has also held other senior positions in Singapore's Health and Education ministries. His current roles promote capacity building and scientific excellence for health products regulation, health policies and systems in Southeast Asia and the Asia-Pacific.

Dr. Yi-Chu Lin

Dr. Yi-Chu Lin is responsible for supervising investigational new drugs (IND), new drugs applications (NDA), post-marketing changes, and other regulatory related issues. Dr. Lin has been working in the regulatory authority for administration of medicinal products since 2010 after receiving Ph.D in Pharmacology from National Taiwan University, bachelor of Pharmacy from Kaohsiung Medical University. Dr. Lin has broad experience in regulatory work along product life cycles, including pharmaceuticals, biologics, cell therapy medicinal products, and gene therapy medicinal products. Dr. Lin conducted the establishment of the biosimilar, vaccine, advanced therapy medicinal products regulations. Furthermore, she led the tasks of setting up the electronic platform of submission and review (ExPress) to facilitate review efficiency.