

# **Regulator's actions to combat COVID-19**

**Yasuhiro Fujiwara, MD. PhD**

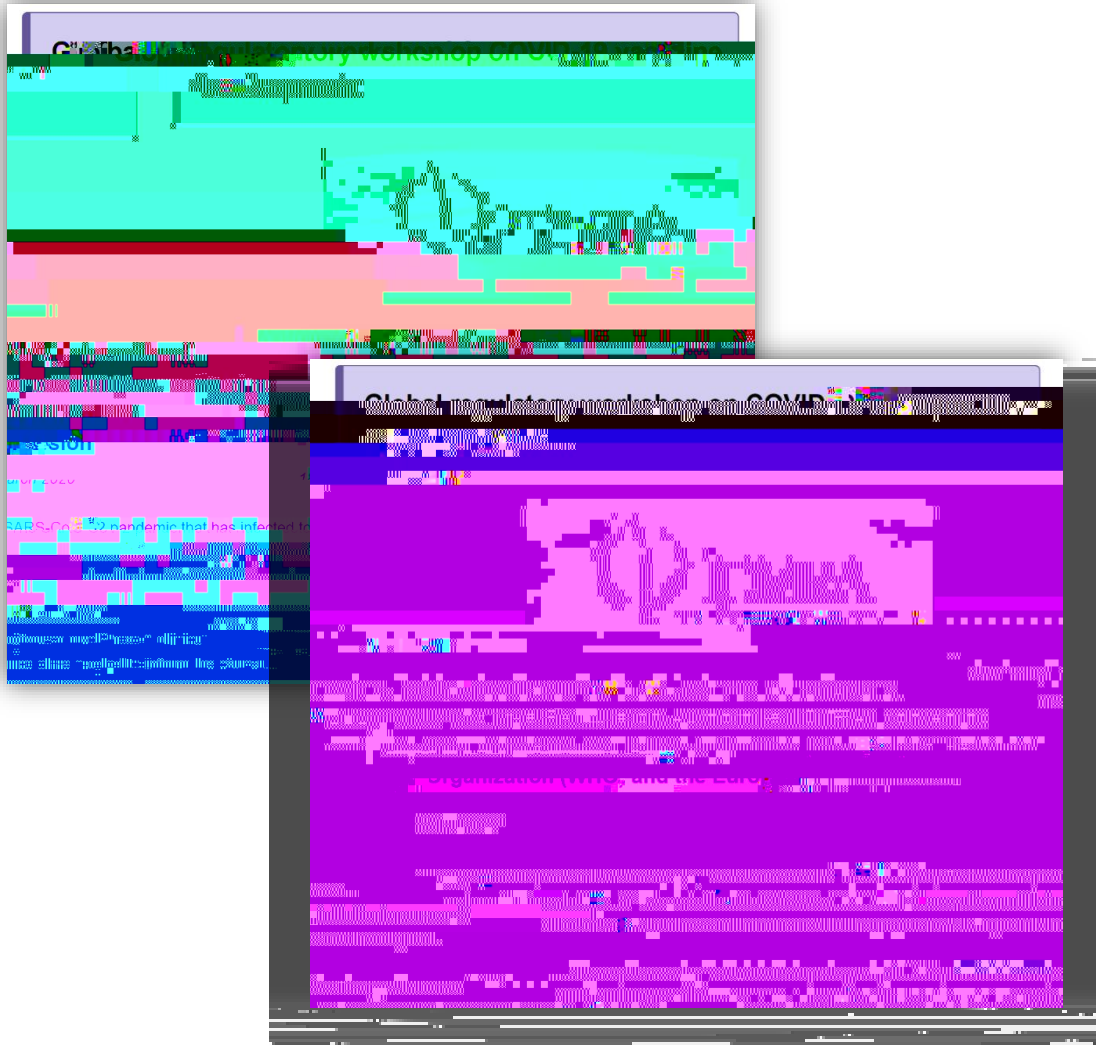
**Chief Executive,**

**Pharmaceuticals and Medical Devices Agency, Japan**





# Discussion on Product Development



**Global regulatory workshop on COVID-19 Real-World Evidence and Observational studies #4 (13 October, 2020)**

**Global regulatory workshop on COVID-19 Real-World Evidence and Observational studies #3 (22 July 2020)**

**Global regulatory workshop on COVID-19 therapeutic development #2 (20 July, 2020)**

**Global regulatory workshop on COVID-19 vaccine development #2 (22 June, 2020)**

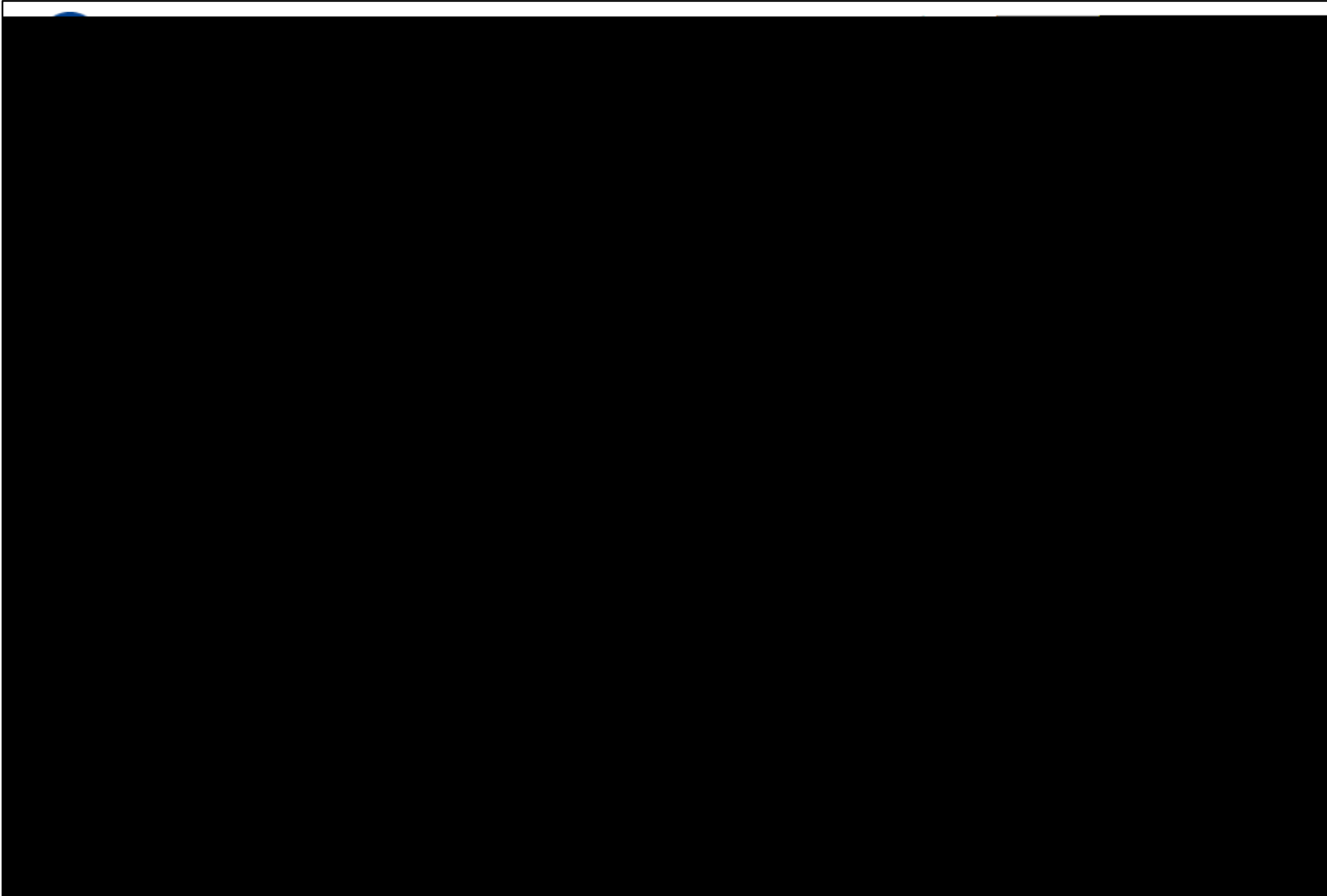
**Global regulatory workshop on COVID-19 Real-World Evidence and Observational studies #2 (19 May, 2020)**

**Global regulatory workshop on COVID-19 Real-World Evidence and Observational studies #1 (6 April, 2020)**

**Global regulatory workshop on COVID-19 therapeutic development #1 (2 April, 2020)**

**Global regulatory workshop on COVID-19 vaccine development #1 (18 March, 2020)**

# Information Sharing with Stakeholders



**Related regulations  
Points to Consider for  
new product  
development  
Approved products  
etc.**

**<https://www.pmda.go.jp/english/index.html>**

# Capacity Building Activities at PMDA

Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs

**Established in April, 2016.**

**Endorsed as Centers of Excellence (CoE)**

**of APEC-LSIF-RHSC**

**Promote capacity building and human resource  
Development through training seminars for Asian  
regulators**

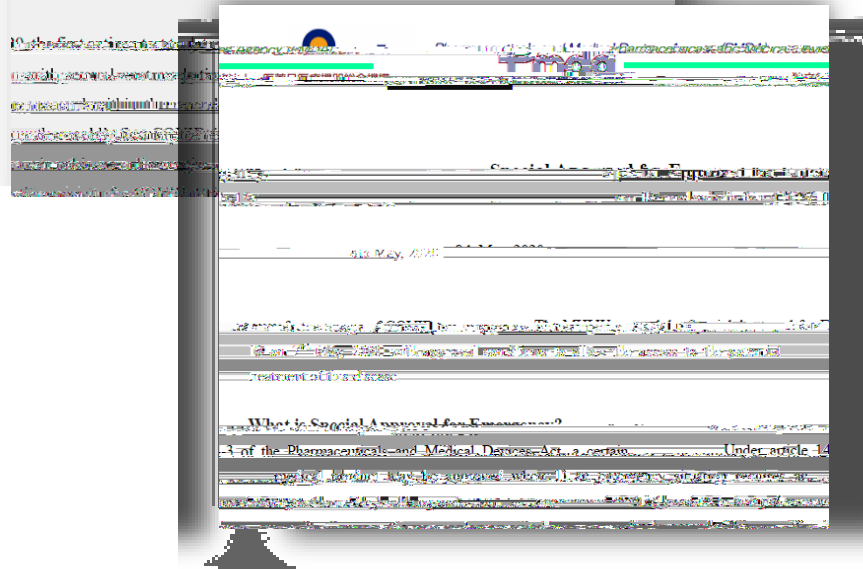
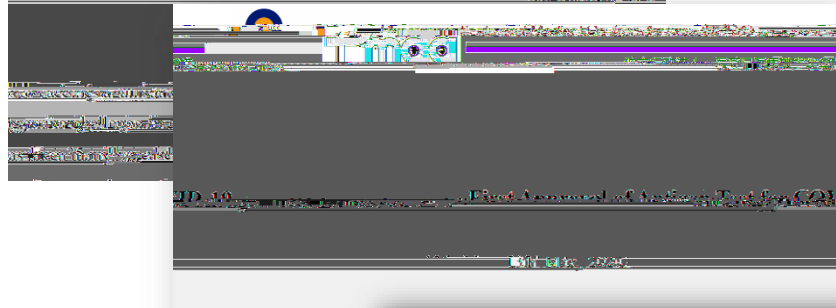
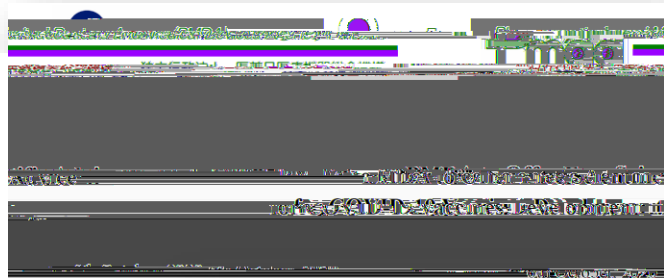
## Action Policy of PMDA-ATC

**Contribute to universal health coverage in Asia through developing a  
foundation for regulatory harmonization in the Asian region.**

## Trainings provided in FY2020

Month	Event	Format
September	Quality Control	Online
September	Industrial Review	Online
October	Pharmaceuticals	Online
December	Pharmaceutical Review	Online
January	Multi-Regional	Online

(As of 15<sup>th</sup> Feb, 2021)

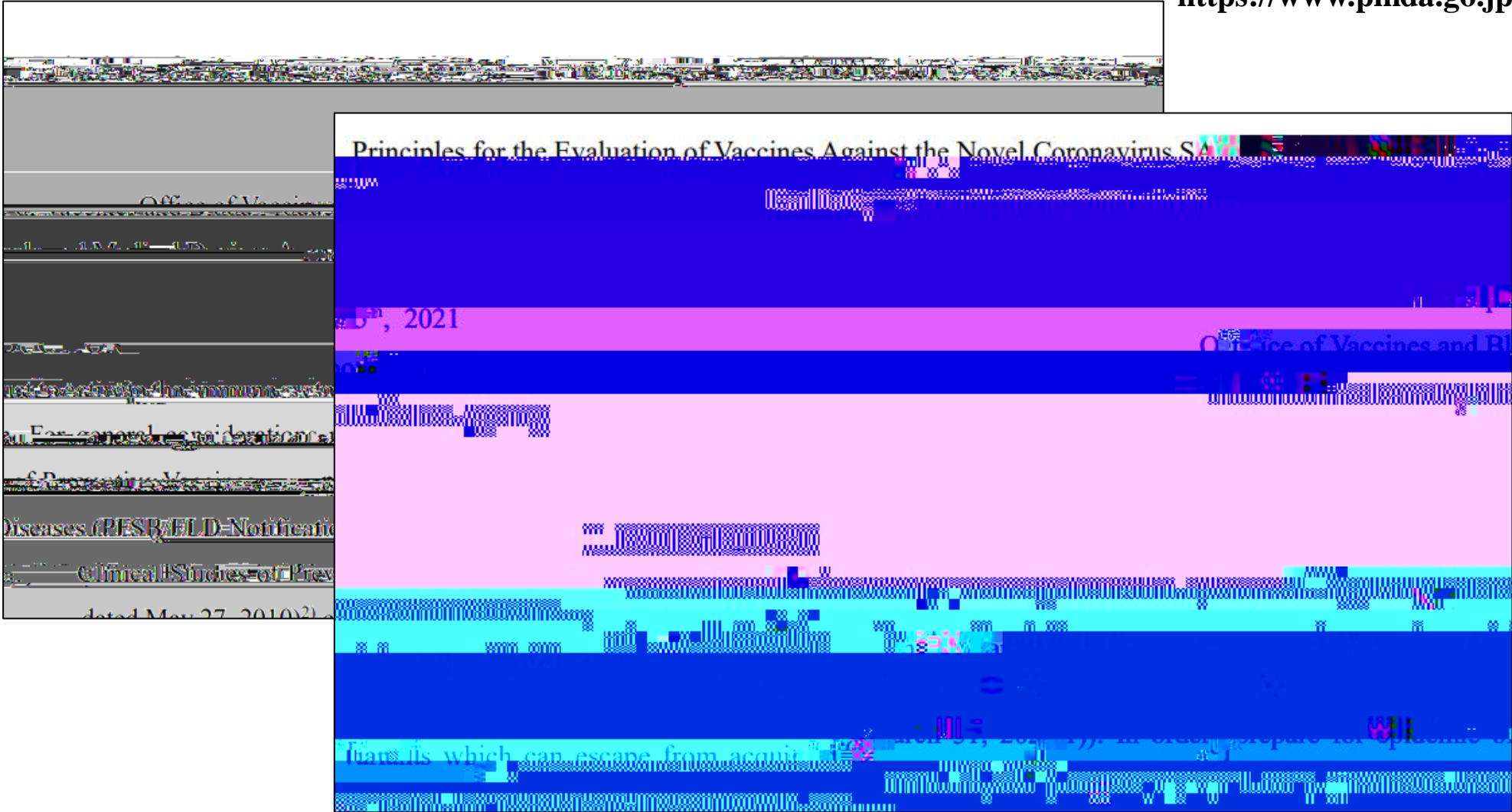


- ▶ **Special Approval for Emergency on First COVID-19 Vaccine in Japan**
- ▶ **PMDA Reveals Principles on Evaluation of COVID-19 Vaccines**
- ▶ **PMDA to Offer Free Scientific Advice**

# To Accelerate SARS-CoV-2 Vaccine Development

<https://www.pmda.go.jp/files/000237021.pdf>

<https://www.pmda.go.jp/files/000240416.pdf>





# Transparency, Convergence, Collaboration



CEPI

