

Regulatory Challenge against COVID-19

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Today's Agenda

- 1) Situation of COVID-19 in Japan**
- 2) Approved Medical Products for COVID-19**
- 3) Regulatory Flexibilities/Agilities during COVID-19**

Situation of COVID-19 in Japan

Number of Cases (As of 0:00, March 14, 2021)

	Number of Cases
PCR tested	8,378,595
PCR tested positive	442,393
Need inpatient treatment (current)	12,312
Death	8,558

https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000164708_00079.html

- State of emergency was declared on April 7
 - Saitama, Chiba, Tokyo, Kanagawa prefectures are still under the state of emergency.
- COVID-19 drug, Remdesivir developed by Gilead Sciences K.K. granted Special Approval for Emergency on May 7, 2020.
- COVID-19 vaccine applied by Pfizer Japan Inc. granted Special Approval for Emergency on Feb. 14, 2021. And vaccination for health care workers started on Feb. 17, 2021.

Approval of COVID-19 products (Medical Device, IVD) (as of March 15)

▶ COVID-19 test kit (IVD)

43 products (26 PCR kits, 17 Antigen test kits)

https://www.mhlw.go.jp/stf/newpage_11332.html (English)



▶ Medical Device

24 products (ventilator, syringe, thermometer, pulse oximeter, etc.)

<https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/000011639.html> (Japanese only)



Regulatory Flexibilities/Agilities during COVID-19

▶ Clinical Trial

Clinical trials for COVID-19 products are allowed to start without waiting 30 days after submission of clinical trial notification if investigation by PMDA is completed.

▶ Marketing Approval

- Expedited review

e.g. review period for COVID-19 test kit (IVD): 12 months → 1~ 2 months

- Priority consultation before application

free of charge

Basic Concept for Review of COVID-19 Test Kits

Limitation on review

- Difficulty of obtaining clinical samples for clinical performance studies
- Unable to submit long-term stability test under the actual storage conditions



Conditions for approval

- Post-marketing studies should be conducted to evaluate the clinical performance
- Post-marketing stability studies should be conducted under actual storage conditions



Thank you for your attention!

Information on COVID-19

MHLW

https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000164708_00079.html

PMDA

<https://www.pmda.go.jp/english/about-pmda/0002.html>