

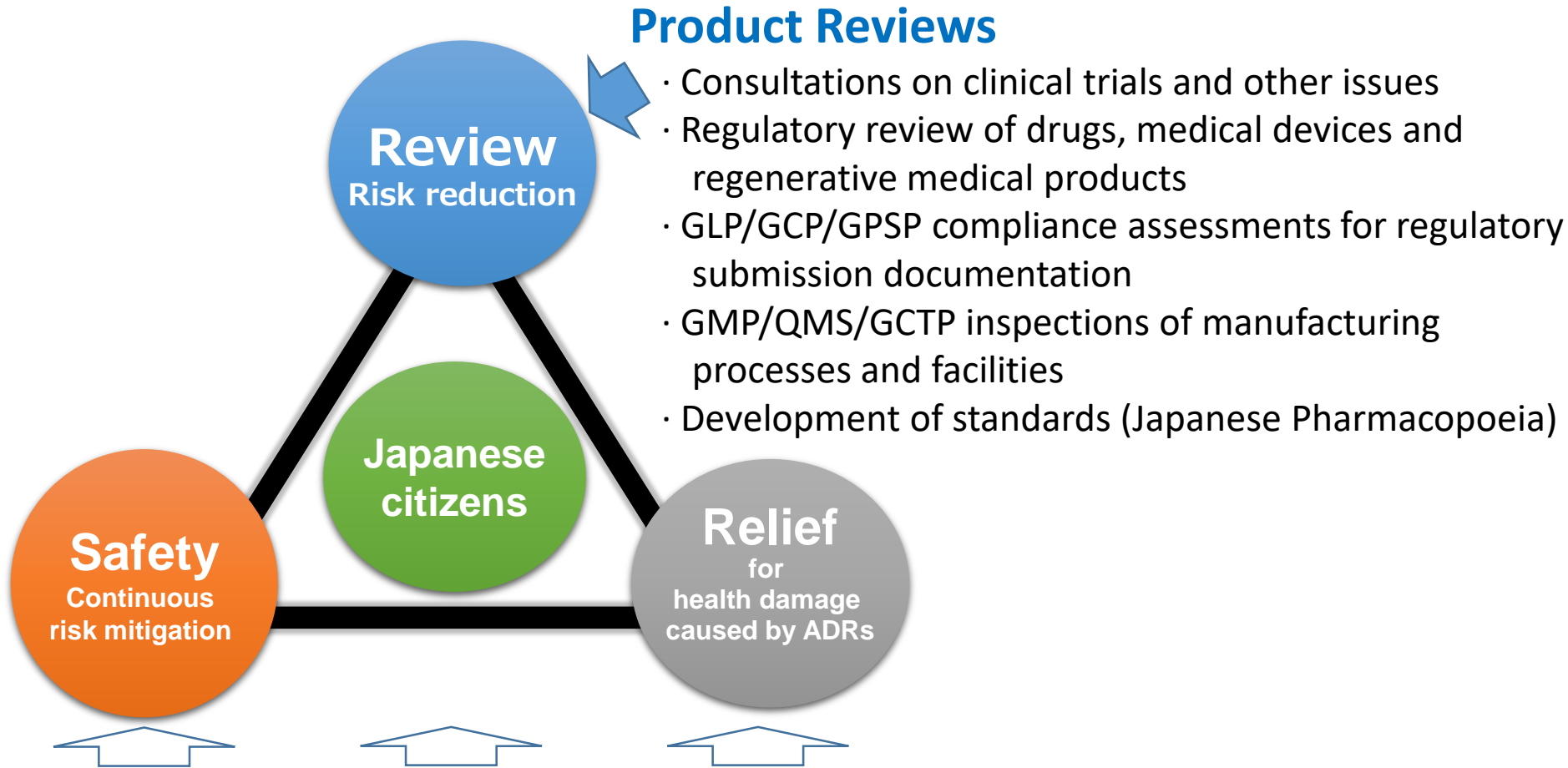
# PMDA's activity against COVID-19

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Office of Review Management    PMDA

# PMDA's Safety Triangle



- Improving quality of services by promoting regulatory science
- Promoting globalization
- Developing the governance/compliance system based on organizational role and social position

# PMDA's Efforts to Combat COVID-19



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## PMDA's Efforts to Combat COVID-19

### PMDA's Efforts to Combat COVID-19

#### Statement by the Chief Executive Dr. FUJIWARA

Issue #	Title	Date
9	<a href="#">Special Approval for Emergency on First COVID-19 Vaccine in Japan</a>	February 16, 2021
8	<a href="#">PMDA Reveals Principles on Evaluation of COVID-19 Vaccines</a>	October 12, 2020
7	<a href="#">PMDA to Offer Free Scientific Advice for COVID-19 Vaccines Development</a>	October 6, 2020
6	<a href="#">For Your Access to Japanese Clinical Trial/Clinical Research Information</a>	June 4, 2020
5	<a href="#">First Approval of Antigen Test for COVID-19</a>	May 13, 2020
4	<a href="#">Special Approval for Emergency on Remdesivir for COVID-19</a>	May 8, 2020
3	<a href="#">Four IVDs Approvals for COVID-19 and Response to the Increased Ventilator Demand</a>	April 21, 2020
2	<a href="#">PMDA Takes Further Steps to Speed up Clinical Development of COVID-19 Products</a>	April 10, 2020
1	<a href="#">PMDA pledge to tackle COVID-19 Pandemic</a>	March 31, 2020

# Actions against COVID-19

March 2020 ~

-Statements by PMDA Chief Executive Dr. Fujiwara-

## 9 statements issued:

- ▶ 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 for COVID-19 Vaccines Development
- ▶ For your Access to Japanese Clinical Trial/Clinical Research Information
- ▶ First Approval of Antigen Test for COVID-19
- ▶ Special Approval for Emergency on Remdesivir for COVID-19
- ▶ Four IVDs Approvals for COVID -19 and Response to the Increased Ventilator Demand
- ▶ PMDA Takes Further Steps to Speed up Clinical Development of COVID-19 Products
- ▶ PMDA pledge to tackle COVID-19 Pandemic

(As of May25, 2021)



### PMDA to Offer Free Scientific Advice for COVID-19 Vaccines Development

6th October, 2020

Ensuring access to vaccines against the SARS-CoV-2 (novel coronavirus) is the most

pressing challenge for  
cases reaching  
actions to address



### First Approval of Antigen Test for COVID-19

13th May, 2020



### Special Approval for Emergency on Remdesivir for COVID-19

8th May, 2020

The MHLW granted the Special Approval for Emergency for treatment of COVID-19 on 7<sup>th</sup> May, 2020 with approval conditions to allow the access to the potential treatment of this disease.

#### What is Special Approval for Emergency?

Under article 14-3 of the Pharmaceuticals and Medical Devices Act, a certain medical product may be approved when 1) an emergency situation requires an unapproved medical product to be used to prevent damage to the public health caused by the spread of diseases, 2) such emergency situation cannot be managed appropriately

# Other Actions against COVID-19

## For COVID-19 Products

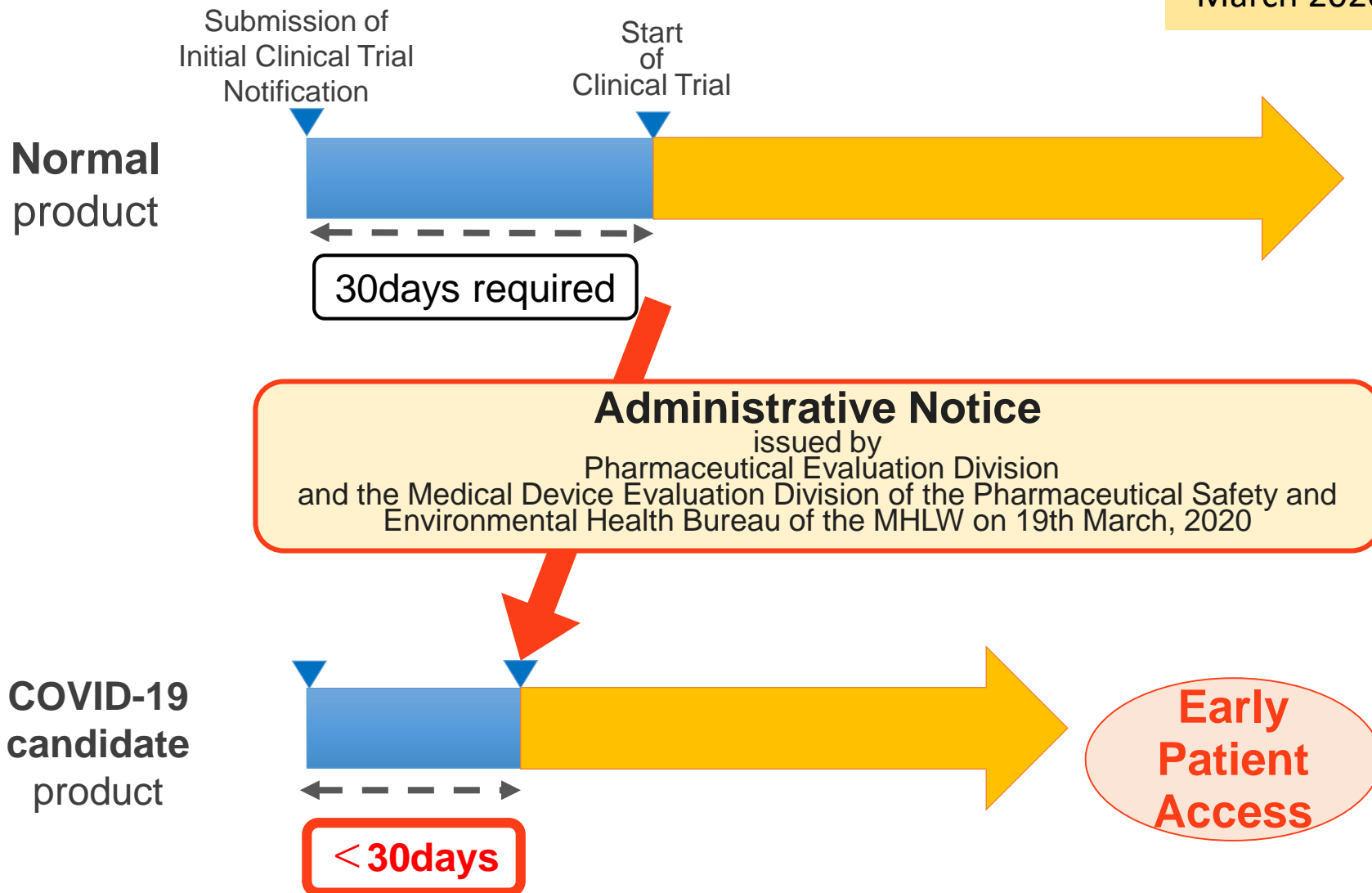
- Drug approval for COVID-19
- IVDs approval for COVID-19
- Close interaction with sponsors, global regulators and WHO
- Allowing quick start of clinical

## For non-COVID-19 Products

- Providing information on how to manage clinical trials

# Allowing Quick Start of Clinical Trials

March 2020 ~



# Q&A on Management of Clinical trials during COVID-19 Pandemic

March 2020 ～

Provides **alternative measures** that can be taken by the sponsor and/or clinical trial site when the process predetermined in the **study protocol is not deemed feasible due to the COVID-19 situation.**

## 新型コロナウイルス感染症の影響下での医薬品、医療機器及び再生医療等製品の治験実施に係るQ&Aについて

現在実施中の医薬品、医療機器及び再生医療等製品の治験において、新型コロナウイルス感染症の影響により治験実施計画書の規定及び通常の手順と異なる対応を取らざるを得ない場合は、被験者の安全確保を最優先とした上で、経緯及び対応の記録を残し、その妥当性について説明できるようにしてください。また、実施医療機関において疑義が生じる場合の対応については、まずは治験依頼者と協議・相談してください。

これまでいただいたお問い合わせに対する回答を、以下にご紹介しますので参考としてください。なお、内容については、今後のお問い合わせに応じて更新いたします。

2020年3月27日作成

2020年4月2日更新

2020年4月21日更新

Q1 実施医療機関に来院できない等により、被験者が治験薬、治験機器又は治験製品（以下「治験薬等」という。）を直接受け取れない場合、実施医療機関から被験者宅に配送してよいのか。（実施医療機関・治験依頼者）

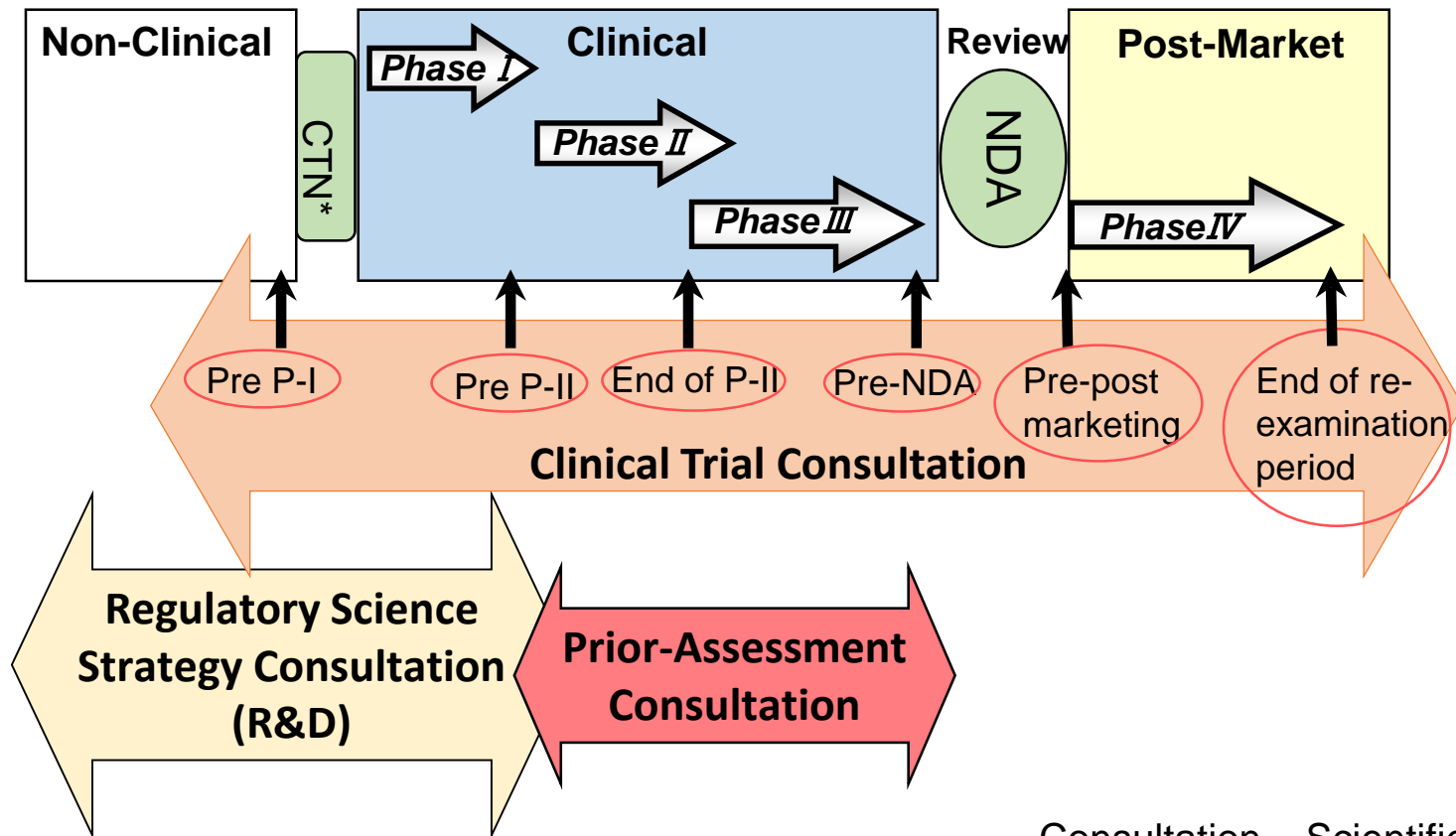
実施医療機関と医薬品GCP省令第39条の2、医療機器GCP省令第59条又は再生医療等製品GCP省令第59条に基づく委託契約を締結した配送業者、または、実施医療機関の治験協力者により、実施医療機関から被験者宅に治験薬等を配送することは可能である。その際、試験デザイン、治験薬等の性質、被験者の状態等を考慮の上、同意を得た被験者において実施医療機関の責任のもと実施すること。なお、運搬中の治験薬等の品質管理に加え、被験者への交付を確実にするための手順を予め定めておくこと。また、経緯及び対応の記録を作成し保存すること。

Q1-2 実施中の治験において、治験薬等を被験者宅に速やかに配送する必要があるため、事前にすべての実施医療機関と配送業者の間で、上記A1に示される医薬品GCP省令第39条の2等の委託契約を締結することが難しい場合、治験依頼者が選定・契約する配送業者により配送してもよいのか。（実施医療機関・治験依頼者）

A1-2 実施医療機関と治験依頼者が協議し、至急の対応を要する場合においては可能である。ただし、治験薬等の品質管理や被験者の個人情報等の取扱いを含めた業務内容を適切に取

# Tools for Early patient Access

## - Consultation Services -



Consultation = Scientific Advice  
CTN\*: clinical trial notification



# Supporting of COVID-19 Vaccines Development

## Principles for the Evaluation of Vaccines Against the SARS-CoV-2

Sep 2020

- On 2nd Sep, 2020 the PMDA published the “Principles for the Evaluation of Vaccines Against the Novel Coronavirus SARS-CoV-2”, presenting basic principles concerning the efficacy and safety evaluation of COVID-19 vaccines in Japan.

## Free Scientific Advice for COVID-19 Vaccines Development

Oct 2020

- On 1st Oct, 2020 the PMDA started to offer free of charge scientific advice meeting for the development of COVID-19 vaccines. In this meeting, vaccine companies and academic research organizations can discuss on overall development strategies including clinical trial protocols with PMDA reviewers of relevant offices, depending on the topics to be discussed.

# Actions against COVID-19

## - Information of Approved Medical Products -

### Medicines

2 product approved

Active Ingredient	Brand Name	Applicant Company	Approval Date
Remesivir	VEKLURY for Intravenous Injection	Gilead Sciences K.K.	May 7, 2020*
Baricitinib	Olumiant Tablets 2mg/ Olumiant Tablets 4mg	Eli Lilly Japan K.K.	Apr 23, 2021

### Vaccines

3 product approved

Active Ingredient	Brand Name	Applicant Company	Approval Date
Coronavirus Modified Uridine RNA Vaccine (SARS-CoV-2)	COMIRNATY intramuscular injection	Pfizer Japan Inc.	Feb 14, 2021*
Coronavirus Modified Uridine RNA Vaccine (SARS-CoV-2)	COVID-19 Vaccine Moderna Intramuscular Injection	Takeda Pharmaceutical Co., Ltd.	May 21, 2021*
COVID-19 Vaccine (SARS-CoV-2) Vaccine (recombinant chimpanzee adenovirus vector)	VAXZEVRIA Intramuscular injection	AstraZeneca K.K.	May 21, 2021*

# Actions against COVID-19

## -Publishing Approval Information-

16 product approved

### Medical Devices

JMDN	Brand Name	Applicant Company	Approval Date
Ventilator for general purpose	NKV-550 Series Ventilator System	NIHON KOHDEN CORPORATION	Apr 24, 2020
Bi-level positive airway pressure unit	Philips Respironics E30 ventilator	Philips Japan, Ltd.	May 1, 2020
Adult ventilator	Philips Trilogy Evo Series	Philips Japan, Ltd.	May 12, 2020
Software for diagnostic X-ray imaging system workstation	COVID-19 Pulmonary image analyses AI program "InferRead CT Pneumonia"	CES Descartes Co., Ltd.	Jun 3, 2020
Adult ventilator	Puritan Bennett 560	Covidien Japan, Inc.	Jun 12, 2020
Adult ventilator	ACOMA Ventilator ART-21EX	ACOMA Medical Industry Co., Ltd.	Jun 19, 2020
Heparin-coated aortic cannula	NSH heparin cannulae	SENKO MEDICAL INSTRUMENT Mfg. CO., Ltd.	Jun 25, 2020
Software for diagnostic X-ray imaging system workstation	COVID-19 pneumonia image Analysis Program Ali-M3	MIC Medical Corp	Jun 29, 2020

JMDN	Brand Name	Applicant Company	Approval Date
Heart-lung bypass system	Heart Lung Machine S5	LivaNova Deutschland GmbH (designated MAH*: LivaNova(Japan)K.K.)	Jul 13, 2020
Multiparameter monitor with critical parameters	IntelliVue Patient Monitors MX750/850	Philips Japan, Ltd.	Jul 31, 2020
Ventilator for general purpose	Evita V Series	Drager Japan, Ltd.	Sep 14, 2020
Neonatal/pediatric ventilator	Babylog VN Series	Drager Japan, Ltd.	Sep 14, 2020
Multiparameter monitor with critical parameters	IntelliVue Patient Monitors	Philips Japan, Ltd.	Sep 17, 2020
Software for central monitor with analytic capability	Philips information Center	Philips Japan, Ltd.	Nov 4, 2020
Ventilator for general purpose	Puritan Bennett 980 series	Covidien Japan Inc.	Jan 8, 2021
Syringe with Needle for general purpose	TOP Syringe MV	TOP Corporation	Feb 10, 2021

As of May 25, 2021

JMDN : Japanese Medical Device nomenclature

\*designated holder of marketing authorization for foreign-manufactured products

# Actions against COVID-19

## -Publishing Approval Information-

64 product approved

### In Vitro Diagnostics

JMDN	Brand Name	Applicant Company	Approval Date
SARS-CoV-2 nucleic acid kit	2019-nCoV Fluorescence Detection Real-time RT-PCR Kit*	Sysmex Corporation	Mar 27, 2020
SARS-CoV-2 nucleic acid kit	Loopamp Novel Coronavirus 2019(SARS-CoV-2) Detection Kit*	Eiken Chemical Co., Ltd.	Mar 31, 2020
SARS-CoV-2 nucleic acid kit	Cobas SARS-CoV-2*	Roche Diagnostic K.K.	Apr 7, 2020
SARS-CoV-2 nucleic acid kit	TaqPath Real Time PCR Reagent Kit for SARS-CoV-2*	Life Technologies Japan Ltd.	Apr 20, 2020
SARS-CoV-2 nucleic acid kit	Xpert Xpress SARS-CoV-2 'Cepheid'*	Beckman Coulter, Inc.	May 8, 2020
SARS-CoV-2 antigen kit	ESPLINE SARS-CoV-2	Fujirebio Inc.	May 13, 2020
SARS-CoV-2 nucleic acid kit	MEBRIGHT SARS-CoV-2 Kit*	Medical & Biological Laboratories Co. Ltd.	May 21, 2020
SARS-CoV-2 nucleic acid kit/ Virus Nucleic Acid Isolation Kit/ Bacterial Nucleic Acid Isolation Kit	FilmArray Respiratory Panel 2.1	bioMérieux Japan Ltd.	Jun 2, 2020

JMDN	Brand Name	Applicant Company	Approval Date
SARS-CoV-2 antigen kit	Lumipulse SARS-CoV-2 Ag	Fujirebio Inc.	Jun 19, 2020
SARS-CoV-2 nucleic acid kit	GENECUBE SARS-CoV-2	TOYOBO CO.,LTD.	Jul 2, 2020
SARS-CoV-2 nucleic acid kit	TRCReady SARS-CoV-2	Tosoh Corporation	Jul 31, 2020
SARS-CoV-2 antigen kit	QuickNavi-COVID 19 Ag	Denka Co., Ltd.	Aug 11, 2020
SARS-CoV-2 nucleic acid kit	SmartAmp SARS-CoV-2	K.K.DNAFORM	Aug 17, 2020
SARS-CoV-2 nucleic acid kit	Aptima SARS-CoV-2	Hologic Japan, Inc.	Aug 18, 2020
SARS-CoV-2 nucleic acid kit	Ampdirect 2019-nCoV Detection Kit	SHIMADZU CORPORATION	Sep 8, 2020
SARS-CoV-2 nucleic acid kit	i-densy Pack SARS-CoV-2	ARKRAY Factory, Inc.	Sep 8, 2020
SARS-CoV-2 antigen kit	ImunoAce SARS-CoV-2/ Capilia SARS-CoV-2	TAUNS LABORATORIES, INC.	Oct 13, 2020
SARS-CoV-2 antigen kit	Lumipulse Presto SARS-CoV-2 Ag	Fujirebio Inc.	Oct 16, 2020
SARS-CoV-2 nucleic acid kit	ID NOW COVID-19	Abbott Diagnostics Medical Co., Ltd.	Oct 20, 2020

# Actions against COVID-19

## -Publishing Approval Information-

### In Vitro Diagnostics (2)

JMDN	Brand Name	Applicant Company	Approval Date
SARS-CoV-2 nucleic acid kit	GENECUBE HQ SARS-CoV-2	TOYOBO CO., Ltd.	Oct 23, 2020
SARS-CoV-2 nucleic acid kit / Influenza virus nucleic acid kit	SGNP nCoV/Flu PCR Detection Kit	SUDx-Biotec Corporation	Oct 23, 2020
SARS-CoV-2 nucleic acid kit	Takara SARS-CoV-2 Direct PCR detection kit	Takara Bio Inc.	Oct 27, 2020
Influenza Virus kit	Lumipluse Flu-A&B	Fujirebio Inc.	Nov 10, 2020
SARS-CoV-2 antigen kit	HISCL SARS-CoV-2 Ag Assay Kit	Sysmex Corporation	Nov 10, 2020
SARS-CoV-2 nucleic acid kit / Influenza virus nucleic acid kit	cobas SARS-CoV-2 & Flu A/B	Roche Diagnostics K.K.	Nov 13, 2020
Influenza virus kit	Lumipulse Presto Flu-A&B	Tujirebio Inc.	Dec 22, 2020
Interferon-λ3 kit	HISCL IFN-λ3 Assay kit	Sysmex Corporation	Dec 22, 2020
SARS-CoV-2 nucleic acid kit	TRCReady SARS-CoV-2i	TOSOH CORPORATION	Jan 19, 2021
SARS-CoV-2 antigen kit	LuminaDx SARS-CoV-2 Ag Test Strip	LuminaDx Japan Co., Ltd.	Jan 19, 2021

JMDN	Brand Name	Applicant Company	Approval Date
SARS-CoV-2 antigen kit	Panbio COVID-19 Ag Rapid Test Device (NASOPHARYNGEAL)/ Panbio TM COVID-19 Ag Rapid test Device (NASAL)	Abbott Diagnostics Medical Co., Ltd.	Jan 22, 2021
SARS-CoV-2 antigen kit	BD Veritor System for Rapid Detection of SARS-CoV-2	Becton, Dickinson and Company	Jan 26, 2021
SARS-CoV-2 antigen kit	PRORAST SARS-CoV-2 Ag ADTest SARS-CoV-2	ADTEC Corporation/LSI medicine Corporation	Jan 29, 2021
Influenza virus nucleic acid kit	Loopamp Influenza B virus Detection Kit	Eiken Chemical Co., Ltd.	Feb 2, 2021
SARS-CoV-2 antigen kit	SARS-CoV-2 Rapid Antigen Test	Rosch Diagnostics K.K.	Feb 9, 2021
SARS-CoV-2 nucleic acid kit	Simprova SARS-CoV-2 Detection Kit	Eiken Chemical Co., Ltd.	Feb 15, 2021
SARS-CoV-2 nucleic acid kit	Takara SARS-CoV-2 & Flu Direct PCR detection kit	Takara Bio Inc.	Feb 15, 2021
SARS-CoV-2 antigen kit	FUJI DRI-CHEM IMMUNO AG HANDY COVID-19 Ag	FUJIFIRM Corporation	Feb 15, 2021
Influenza virus nucleic acid kit	Simprova Influenza A virus Detection kit	Eiken Chemical Co., Ltd.	Feb 15, 2021

As of May 25, 2021

# Actions against COVID-19

## -Publishing Approval Information-

### In Vitro Diagnostics (3)

JMDN	Brand Name	Applicant Company	Approval Date
Influenza virus nucleic acid kit	Simprova Influenza B virus Detection kit	Eiken Chemical Co., Ltd.	Feb 15, 2021
SARS-CoV-2 antigen kit	Panbio COVID-19 Ag Rapid Test Device (NASOPHARYNGEAL)/ Panbio TM COVID-19 Ag Rapid Test Device (NASAL)	Abbott Diagnostics Medical Co., Ltd.	Jan 22, 2021
SARS-CoV-2 antigen kit	BD Veritor System for Rapid Detection of SARS-CoV-2	Becton, Dickinson and Company	Jan 26, 2021
SARS-CoV-2 antigen kit	PRORAST SARS-CoV-2 Ag ADTest SARS-CoV-2	ADTEC Corporation/LSI Medience Corporation	Jan 29, 2021
Influenza Virus nucleic acid kit	Loopamp Influenza B virus Detection kit	Eiken Chemical Co., Ltd.	Feb 2, 2021
SARS-CoV-2 antigen kit	SARS-CoV-2 Rapid Antigen Test	Roche Diagnostics K.K.	Feb 9, 2021
SARS-CoV-2 nucleic acid kit	Simprova SARS-CoV-2 Detection kit	Eiken Chemical Co., Ltd.	Feb 15, 2021
SARS-CoV-2 nucleic acid kit	Takara SARS-CoV-2 & Flu Direct PCR detection kit	Takara Bio Inc.	Feb 15, 2021
SARS-CoV-2 antigen kit	FUJI DRI-CHEM IMMUNO AG HANDY COVID-19 Ag	FUJIFIRM Corporation	Feb 15, 2021

JMDN	Brand Name	Applicant Company	Approval Date
Influenza Virus nucleic acid kit	Simprova Influenza A virus Detection kit	Eiken Chemical Co., Ltd.	Feb 15, 2021
Influenza Virus nucleic acid kit	Simprova Influenza B virus Detection kit	Eiken Chemical Co., Ltd.	Feb 15, 2021
SARS-CoV-2 nucleic acid kit	Smart Gene SARS-CoV-2	MIZUHO MEDY Co., Ltd.	Feb 18, 2021
SARS-CoV-2 antigen kit	Sofia SARS Antigen FIA	Quidel Corporation	Feb 18, 2021
Influenza Virus kit	HISCL Influenza Assay Kit	Sysmex Corporation	Feb 18, 2021
SARS-CoV-2 nucleic acid kit	Alinity m system SARS-CoV-2	Abbott Japan LLC	Feb 24, 2021
SARS-CoV-2 antigen kit	Quick Chaser Auto SARS-CoV-2	MIZUHO MEDY Co., Ltd.	Mar 2, 2021
SARS-CoV-2 antigen kit	FUJI DRI-CHEM IMMUNO AG CARTRIDGE COVID-19 Ag	MIZUHO MEDY Co., Ltd.	Mar 2, 2021
SARS-CoV-2 nucleic acid kit / Influenza Virus nucleic acid kit	Cobas Liat SARS-CoV-2 & Flu A/B	Roche Diagnostics K.K.	Mar 12, 2021
SARS-CoV-2 antigen kit	ALSONIC COVID-19 Ag	Alfresa Pharma Corporation	Mar 12, 2021

As of May 25, 2021

# Actions against COVID-19

## -Publishing Approval Information-

### In Vitro Diagnostics (4)

JMDN	Brand Name	Applicant Company	Approval Date
SARS-CoV-2 antigen kit	KBM Line Check nCoV (Stick Type)	KOHJIN BIO CO., LTD.	Mar 17, 2021
SARS-CoV-2 antigen kit	Elecsys SARS-CoV-2 Antigen	Roche Diagnostics K.K.	Mar 17, 2021
SARS-CoV-2 nucleic acid kit / Influenza virus nucleic acid kit	Xpert Xpress SARS-CoV-2/Flu'Cepheid'	Beckman Coulter, Inc.	Apr 14, 2021
SARS-CoV-2 nucleic acid kit	DetectAmp SARS-CoV-2 RT-PCR Kit	Sysmex Corporation	Apr 14, 2021
SARS-CoV-2 antigen kit / Influenza Virus kit	COVID-19 and Influenza A+B Antigen Combo Test (NichireiBio)	Nichirei Biosciences Inc.	Apr 14, 2021
SARS-CoV-2 antigen kit	ImmunoArrow SARS-CoV-2	TOYOBO CO., LTD.	May 12, 2021
SARS-CoV-2 antigen kit	VITROS SARS-CoV-2 Antigen	ORTHO-CLINICAL DIAGNOSTICS K.K.	May 12, 2021

\* Due to the addition of specimen types to COVID-19 Manual by the National Institute of Infectious Diseases, partial change was approved on June 2 to add saliva as a specimen type to those already approved, e.g. specimen obtained from bronchoalveolar lavage and nasopharyngeal swabs.