Latest trend of pharmaceutical, medical device regulation, and international cooperation of Japan

FUJIWARA Yasuhiro, M.D., Ph.D.

Chief Executive, PMDA

21st December 2021

5th India -Japan Medical Products Regulatory Symposium

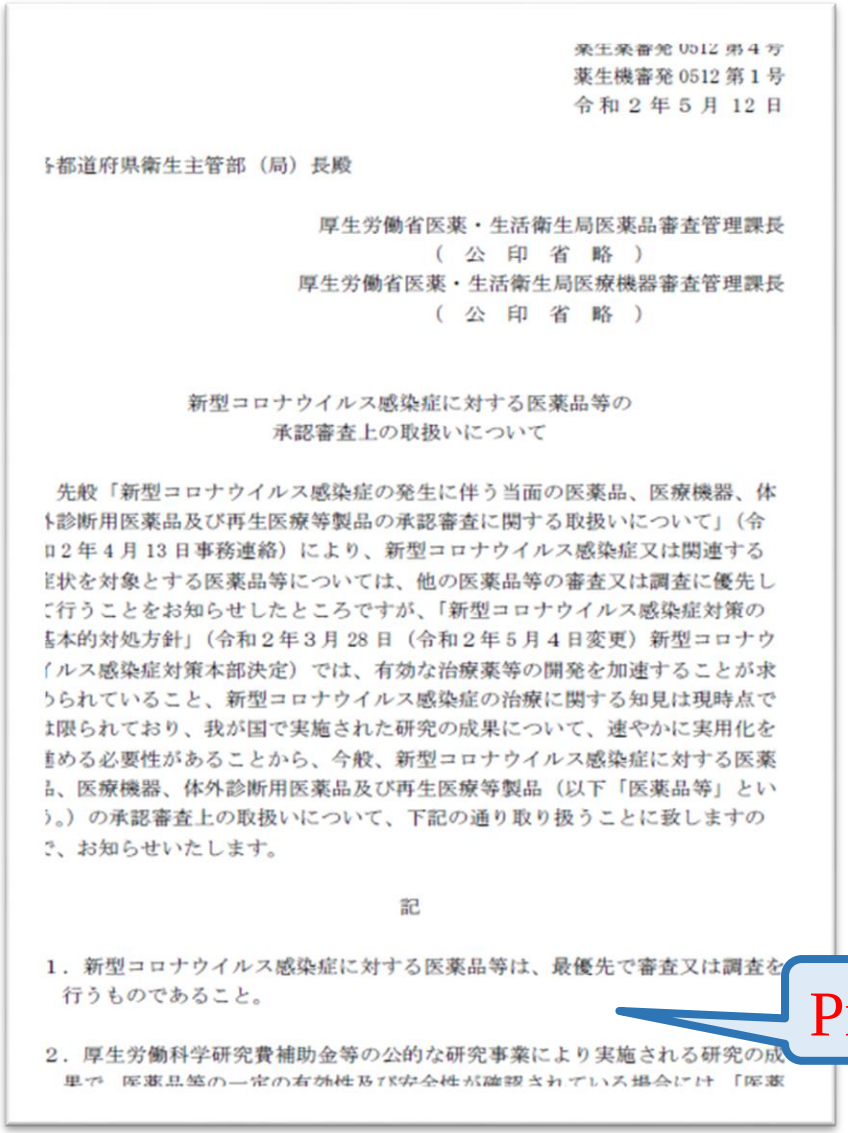
Amendment of PMD Act (in Dec, 2019)

Introduction of new approval schemes into the PMD Act

- SAKIGAKE Designation Scheme
- Conditional Early Approval
- Modified scheme for a technology which requires continuous improvement such as AI
- Priority review of products for specific categories

Speedy Approvals of COVID-19 Product（As of 2nd December, 2021）

Administrative Notice issued in 12 May, 2020※1



薬生薬審発 0512 第４号
薬生機審発 0512 第１号
令和２年５月12日

各都道府県衛生主管部（局）長殿

厚生労働省医薬・生活衛生局医薬品審査管理課長
（公印省略）
厚生労働省医薬・生活衛生局医療機器審査管理課長
（公印省略）

新型コロナウイルス感染症に対する医薬品等の
承認審査上の取扱いについて

先般「新型コロナウイルス感染症の発生に伴う当面の医薬品、医療機器、体外診断用医薬品及び再生医療等製品の承認審査に関する取扱いについて」（令和２年４月13日事務連絡）により、新型コロナウイルス感染症又は関連する症状を対象とする医薬品等については、他の医薬品等の審査又は調査に優先して行うことをお知らせしたところですが、「新型コロナウイルス感染症対策の基本的対処方針」（令和２年３月28日（令和２年５月４日変更）新型コロナウイルス感染症対策本部決定）では、有効な治療薬等の開発を加速することが求められていること、新型コロナウイルス感染症の治療に関する知見は現時点では限られており、我が国で実施された研究の成果について、速やかに実用化を進める必要性があることから、今般、新型コロナウイルス感染症に対する医薬品、医療機器、体外診断用医薬品及び再生医療等製品（以下「医薬品等」という。）の承認審査上の取扱いについて、下記の通り取り扱うことに致しますので、お知らせいたします。

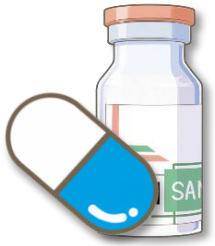
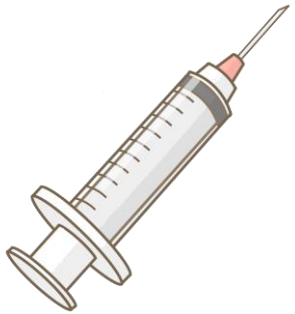
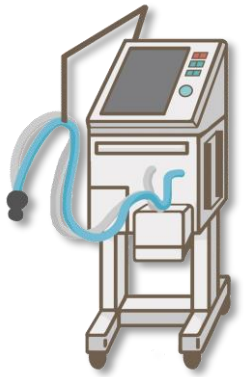
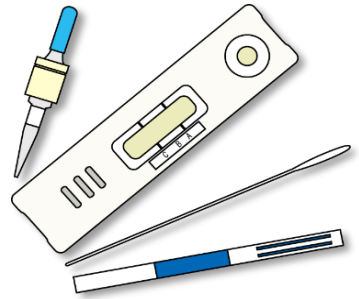
記

１．新型コロナウイルス感染症に対する医薬品等は、最優先で審査又は調査を行うものであること。

２．厚生労働科学研究費補助金等の公的な研究事業により実施される研究の成果で、医薬品等の一定の有効性及び安全性が確認されている場合には、「医薬

Publishing Approval Information in English
URL: https://www.pmda.go.jp/english/about-pmda/0002.html

The number of approved products（As of 15 February, 2021）

Drugs	Vaccines	Medical Devices	IVDs
			
4 product	**3** product	**23** products	**77** products

Priority review for COVID-19 candidate products

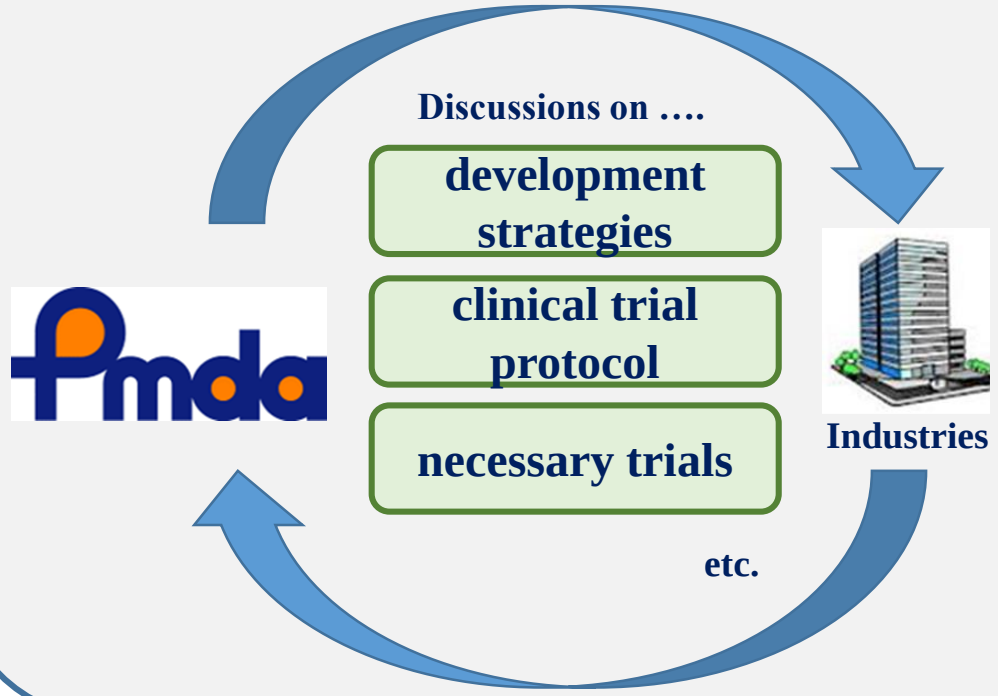
※1 https://www.pmda.go.jp/files/000235010.pdf

Close Interaction with Industry

Many different types of meetings with products developers such as…

From 1st Oct, 2020

Free **Scientific Advice**
for COVID-19 Vaccines Development



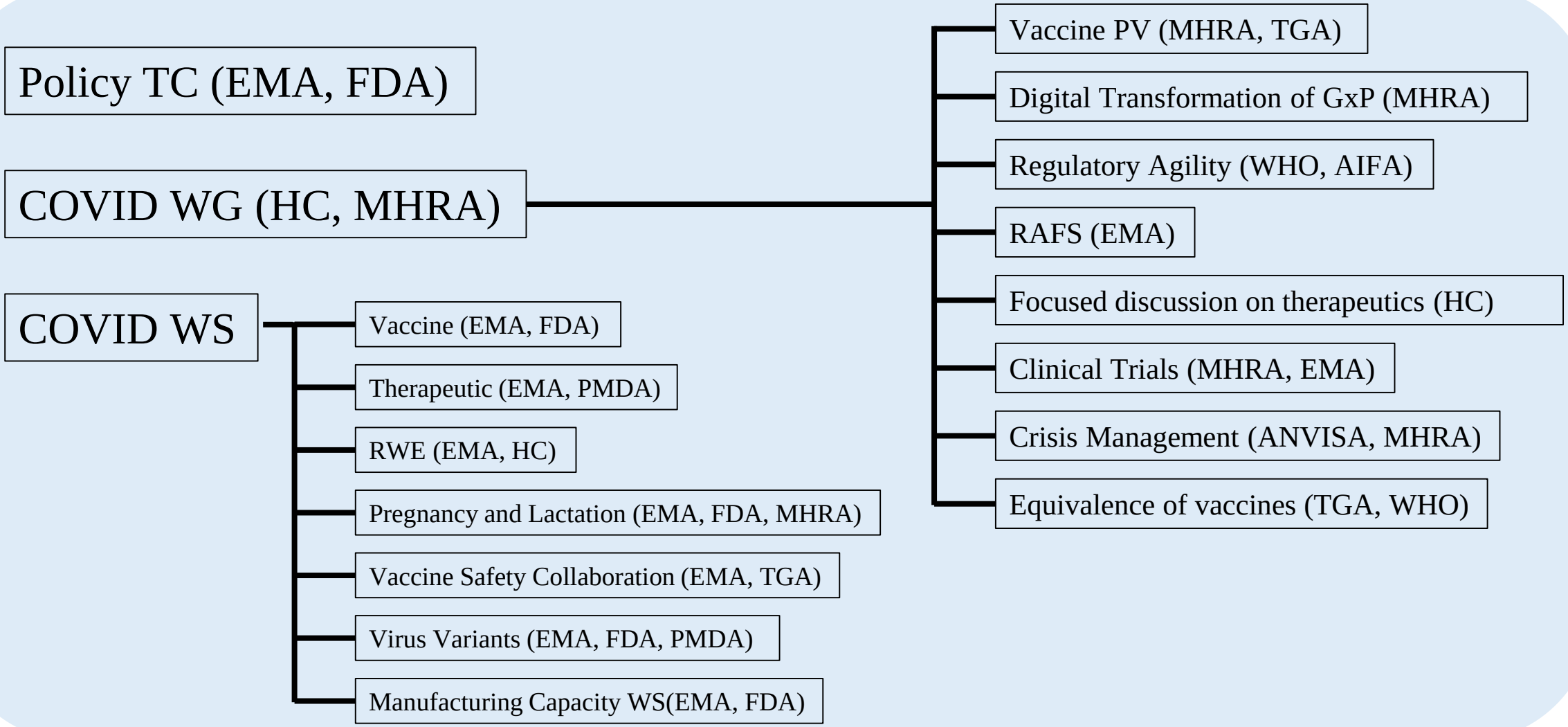
- As many times as necessary
- No waiting time
- Free of charge

Streamlined development for COVID-19 products

https://www.pmda.go.jp/review-services/f2f-pre/strategies/0010.html (Japanese only)

International Collaboration for COVID-19 in ICMRA

ICMRA: International Coalition of Medicines Regulatory Authorities

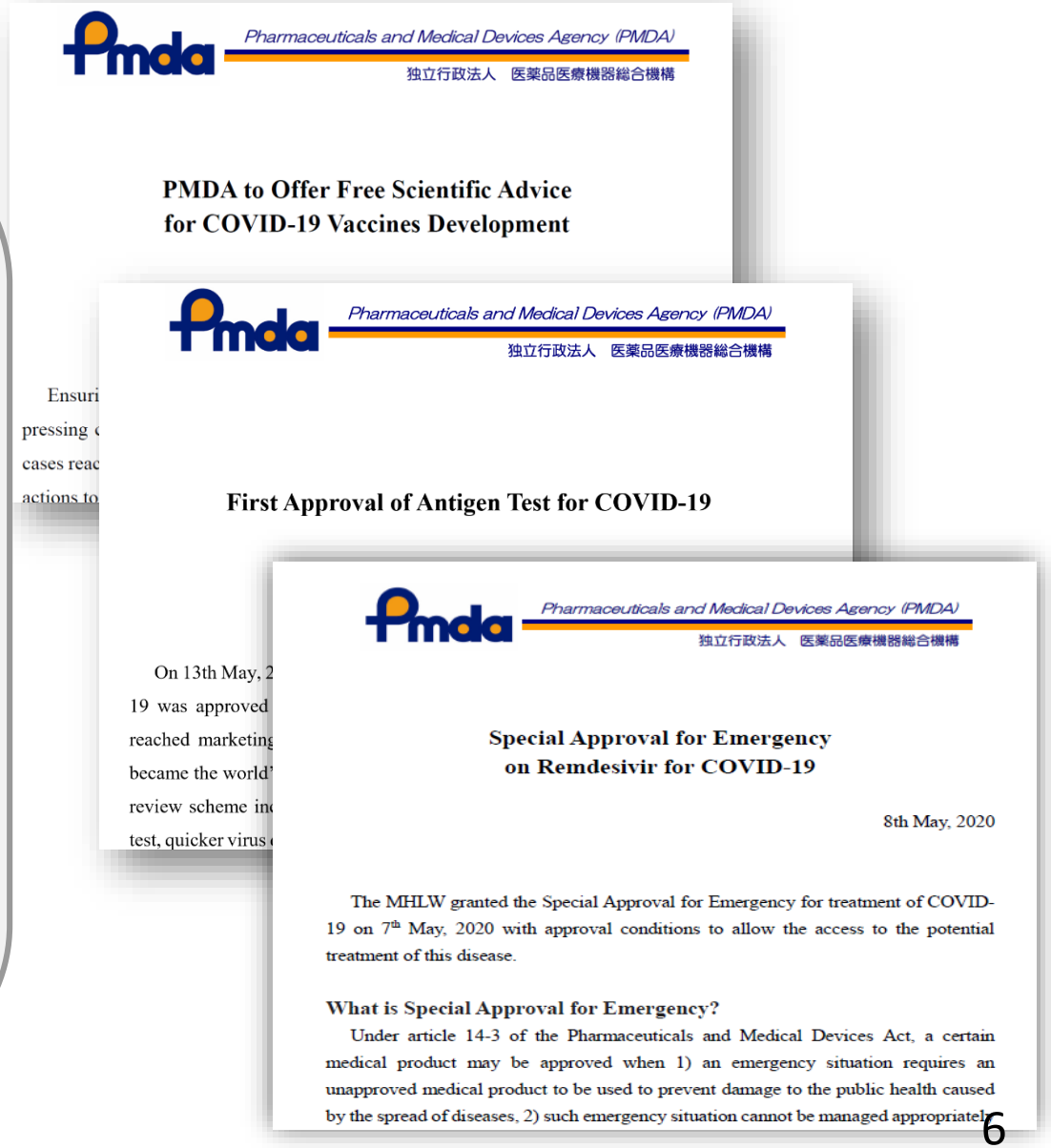


https://www.pmda.go.jp/english/int-activities/int-harmony/icmra/0001.html

Statements by the Chief Executive Dr. FUJIWARA

9 statements issued:

- PMDA pledge to tackle COVID-19 Pandemic
- PMDA Takes Further Steps to Speed up Clinical Development of COVID-19 Products
- Four IVDs Approvals for COVID-19 and Response to the Increased Ventilator Demand
- Special Approval for Emergency on Remdesivir for COVID-19
- First Approval of Antigen Test for COVID-19
- For Your Access to Japanese Clinical Trial/Clinical Research Information
- PMDA to Offer Free Scientific Advice for COVID-19 Vaccines Development
- PMDA Reveals Principles on Evaluation of COVID-19 Vaccines
- Special Approval for Emergency on First COVID-19 Vaccine in Japan



As of 2nd December, 2021

New consultation for SaMD at PMDA

Comprehensive consultation for SaMD

Determine whether the product is MD or Non MD	Review the developed product	Consult the reimbursement prices
MHLW, Compliance and Narcotics Division	**PMDA, Office of SaMD** **Newly established**	**MHLW, Economic Affairs Division**
Consultation regarding the determination of whether or not software under development is classified as a medical device under the PMDA Act.	Pre-consultation before each consultation (pre-development consultation, clinical trial protocol consultation, etc.) conducted by PMDA.	Various consultations regarding medical insurance.

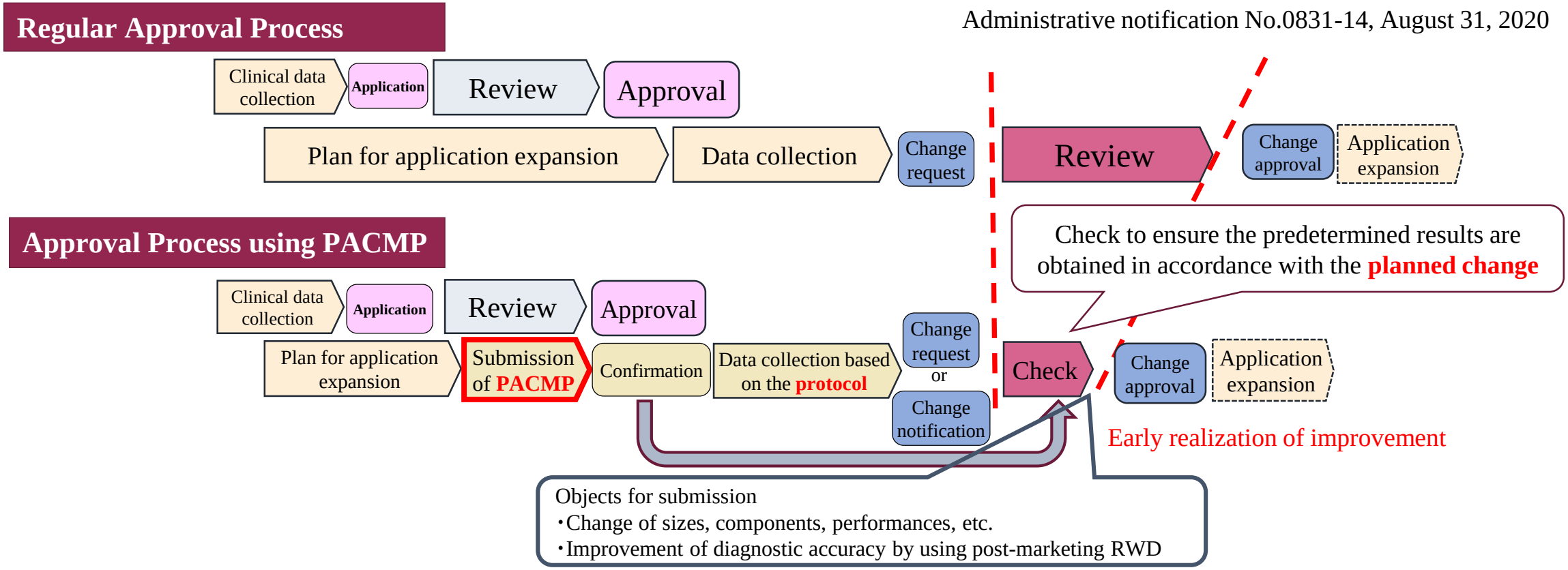
SaMD : Software as a Medical Device

Introduction of an approval pathway based on properties of medical devices

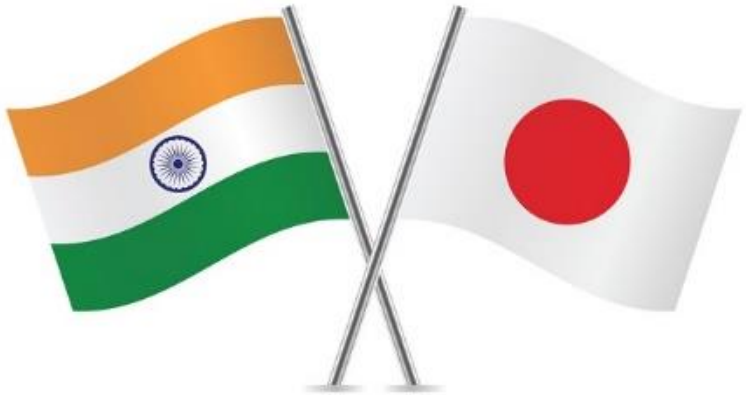
○ Introduction of an approval review system that enables continuous improvements of medical devices with improvements expected* by checking a change plan during the review process and approving partial changes in approved items within the predetermined range promptly

*Medical devices of which performance consistently changes after launch such as medical devices with AI, improvements of medical devices using post-marketing real world data (RWD, data from clinical practices), addition of option parts for improved usability, etc.

Administrative notification No.0831-14, August 31, 2020



→ Improvement Design within Approval for Timely Evaluation and Notice (IDATEN)



Work together with transparency
for patients/citizens needs
in own country and globally