New Approach for GMP/GCTP Compliance Inspection System

Product category-based Inspection

GMP/GCTP Compliance Inspection System in Japan

Conventional system (Basic approch)

- GMP/GCTP inspections are to be conducted for the manufacturing sites based on applications from marketing authorization holders (MAHs), at the time of new approval of products, at the time of partial changes, and every 5 years after approval of the products.
- Many manufacturing sites have manufactured products of multiple MAHs, and the date of approval differs for each product. Thus, during 5 years, frequent inspections were required for one manufacturing site.

Introduce a "**Product Category-based inspection" as an option**

(enforced in August 2021)

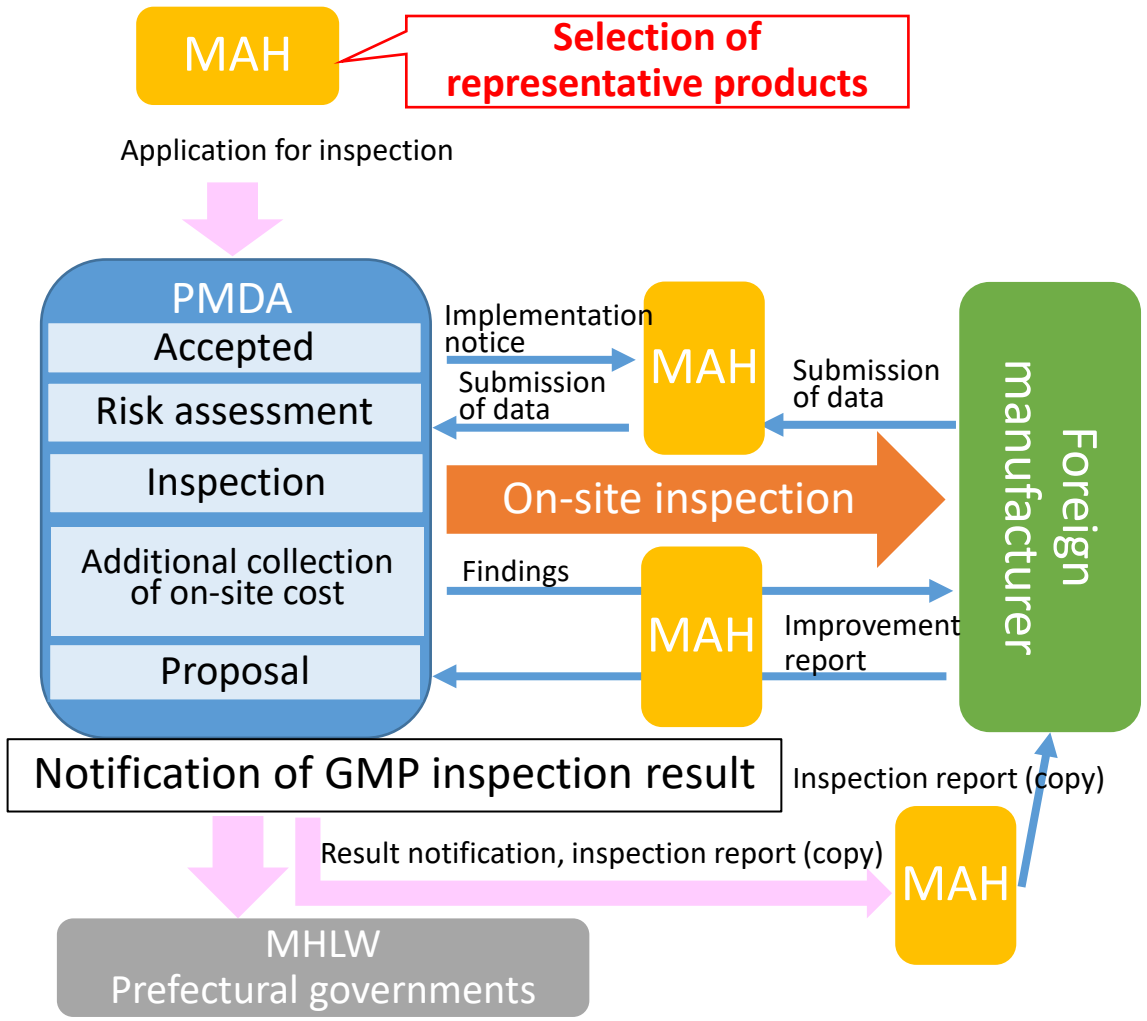
PMDA

Comparison between a Basic approach and the Optional approach

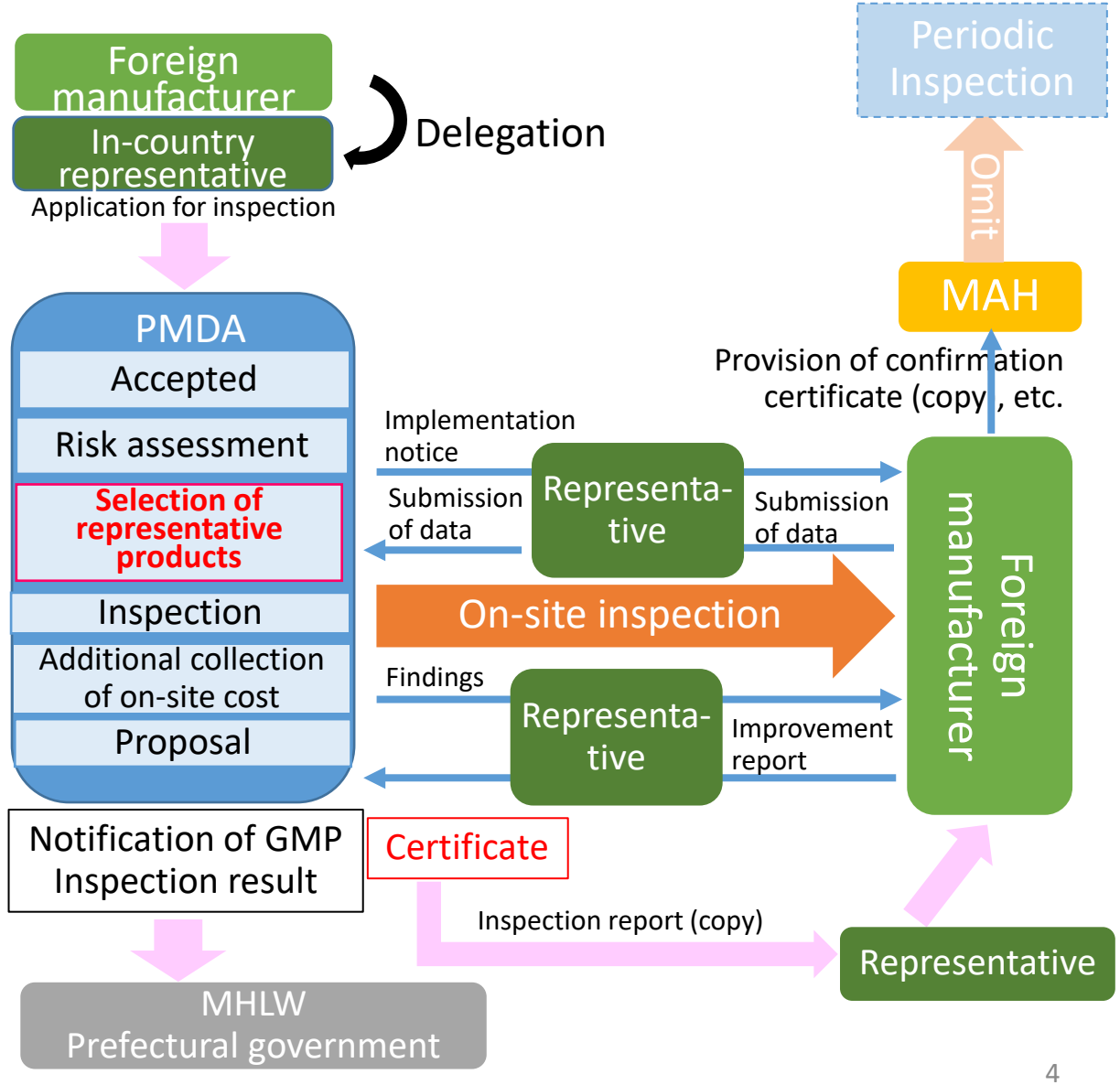
Basic approach (Periodic inspection)		Optional approach (Product category-based Inspection)
Marketing authorization holder	Applicant	**Manufacturer*** *Manufacturing sites licensed/certified/registered under the provisions of Article 13, etc. of the Act Manufacturing sites of drug substance intermediates without license, etc., external testing institutions, etc. are excluded.
For each product (Applications may be made collectively for each MAH/manufacturing site.)	Application unit	**For each manufacturing process category**
Every 5 years after obtaining approval (Applications may be moved forward according to the timing of renewal of manufacturing license, etc.)	Timing of application	**Optionally** (applications should be made in a planned manner so that the Certificate, which is effective at the time of every 5 years after approval of the product for which the periodic inspection is intended to be omitted, is issued)
A legal obligation is imposed, and the failure falls under a violation of Article 14, Paragraph 7 of the Act (Cancellation of approval, order for improvement, etc.)	Action due to failure of application	**Excluded from a violation of laws and regulations** (However, the periodic inspection may not be omitted, and accordingly, the failure may fall under a violation described in the left column.)
Issuance of compliance inspection result notification (no concept of expiry date)	Notification of inspection results	**Issuance of the Certificate** (expiry date: **3 years**)

Procedures of a Basic approach and the Optional approach

◆ Basic approach (Periodic inspection)

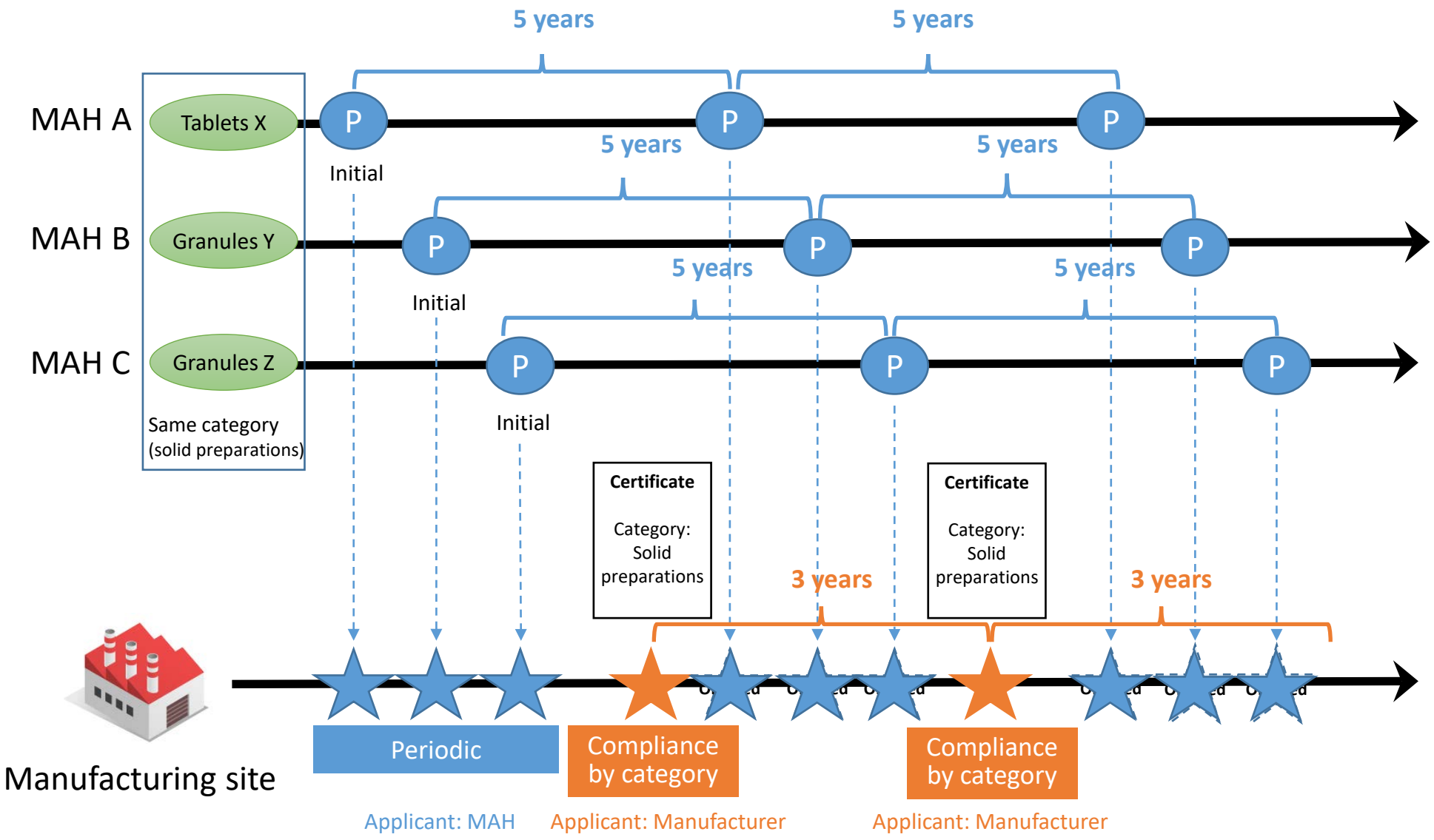


◆ Optional approach (Product category-based Inspection)



MAH: Market Authorization Holder
MHLW: Ministry of Health, Labour and Welfare

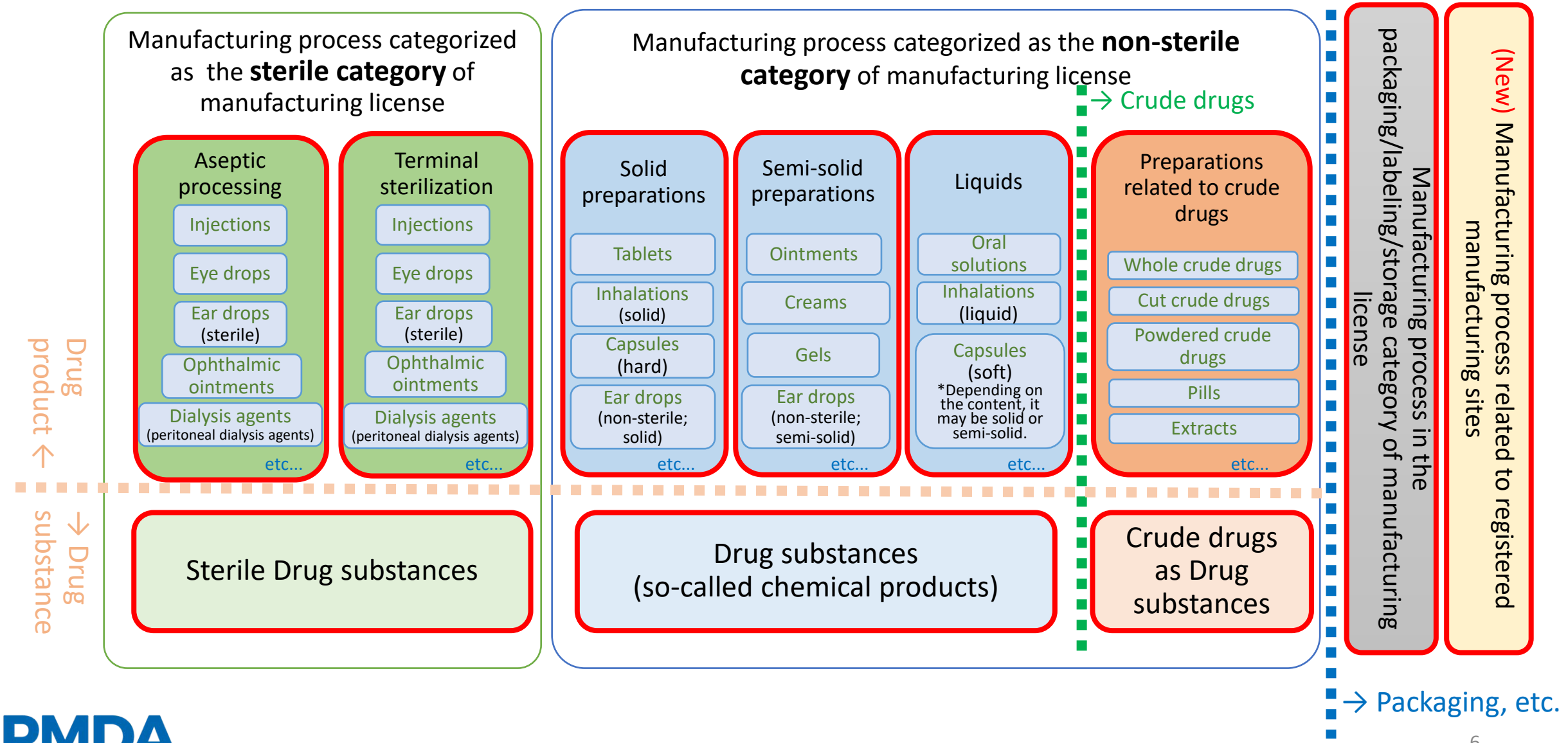
Example of omission of periodic Inspection based on the Certificate



Product Categories

Domestic Inspection: Prefectures are in charge
Overseas Inspection: PMDA is in charge

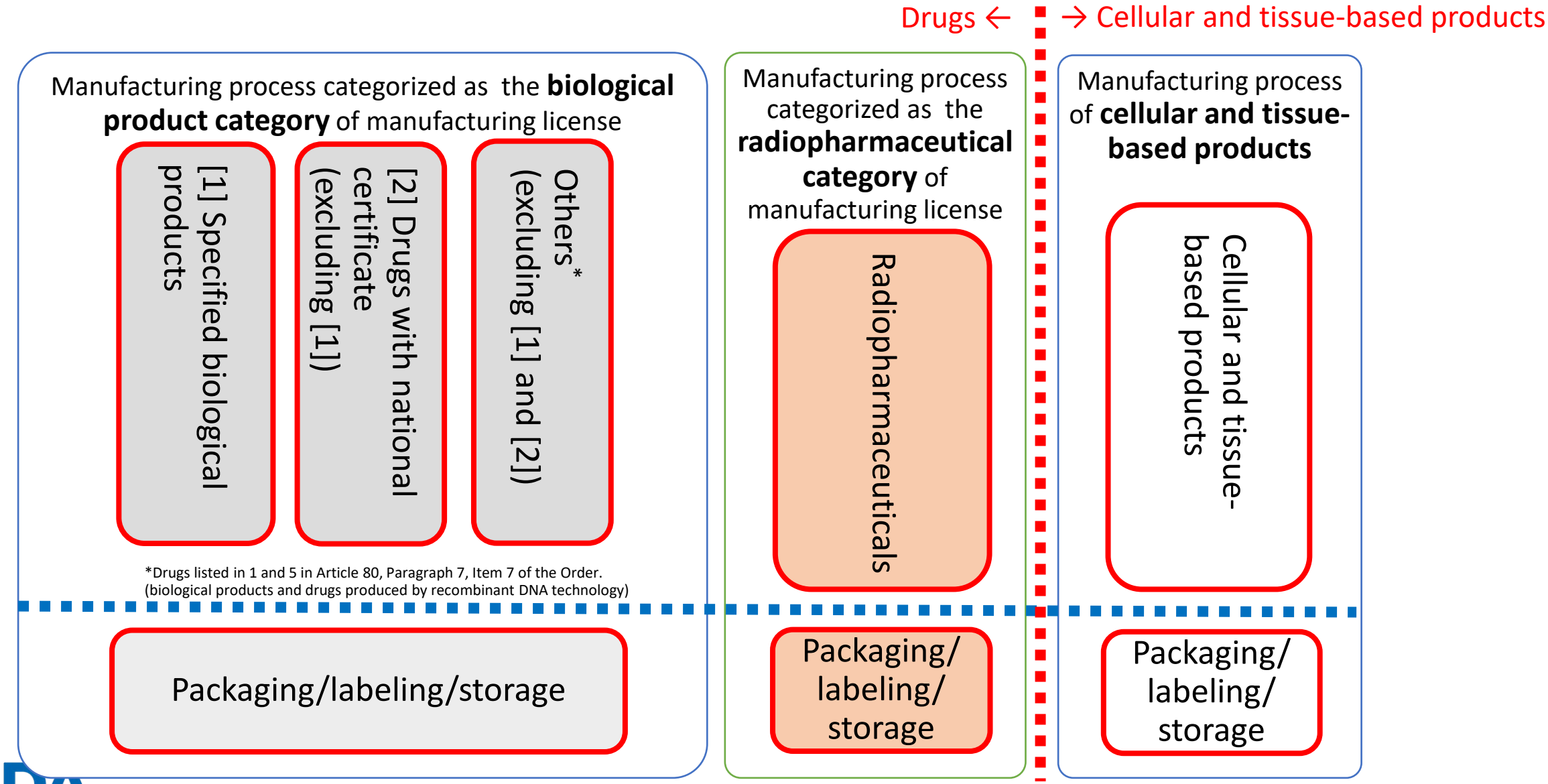
Categories to be described in the Certificate



Product Categories

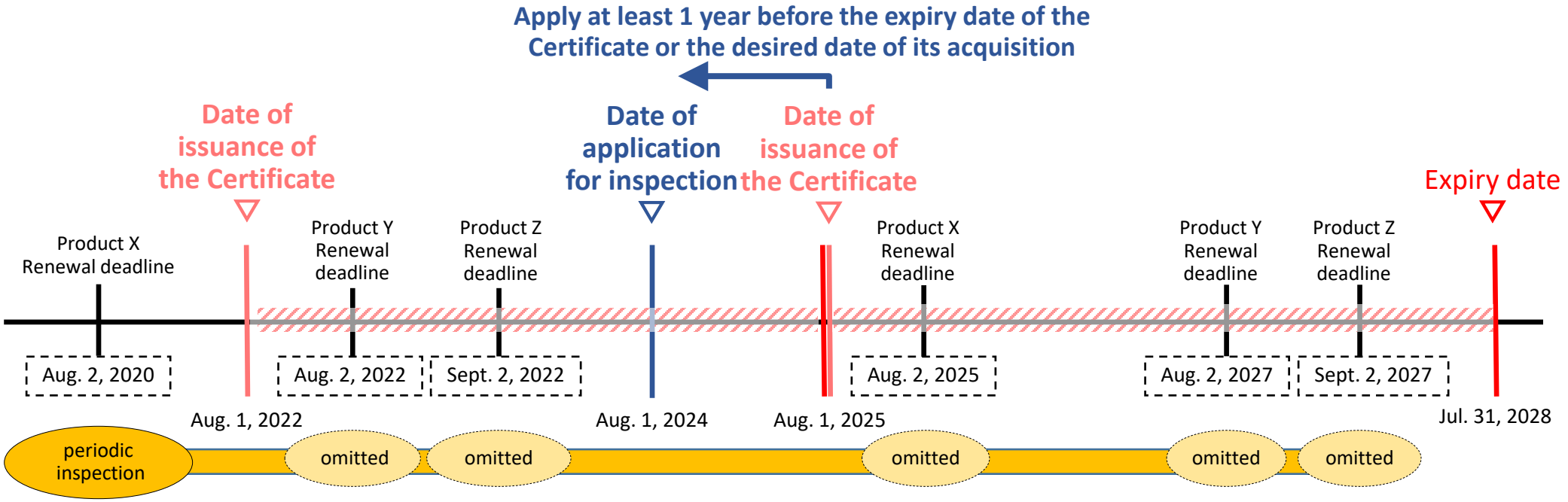
PMDA is in charge

Categories to be described in the Certificate



Standard paperwork period, etc. for Product Category-based Inspection

- The period (standard paperwork period) required for PMDA's inspection related to Product Category-based Inspeciton is 1 year (6 months for new, periodic, and partial changes).
- The applicant needs to apply for the inspection to the PMDA by the day 1 year before the expiry date of the Certificate or the desired date of its acquisition.



- The application for periodic inspection may be omitted only if the Certificate effective at the renewal deadline for each product has been issued.
- If the Certificate is not issued by the renewal deadline for the product, the periodic inspection may not be omitted, and it is necessary to undergo the periodic inspection.