

# Case study : Introduction of GHTF documents

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# Revision of PAL 2002

- ❁ GHTF documents such as MD Classification, the Essential Principles and STED were introduced into national legislation, the Pharmaceutical Affairs Law (PAL), by its revision 2002.
- ❁ Japan could transpose GHTF documents without major changes from their original forms after intensive and constructive discussion among interested parties.  
(Japan has been involved drafting process of GHTF documents under the policy that the GHTF document, in principle, should be enough to be introduced into national regulations in their original forms)
- ❁ The revised PAL has been entered into force in 2005.

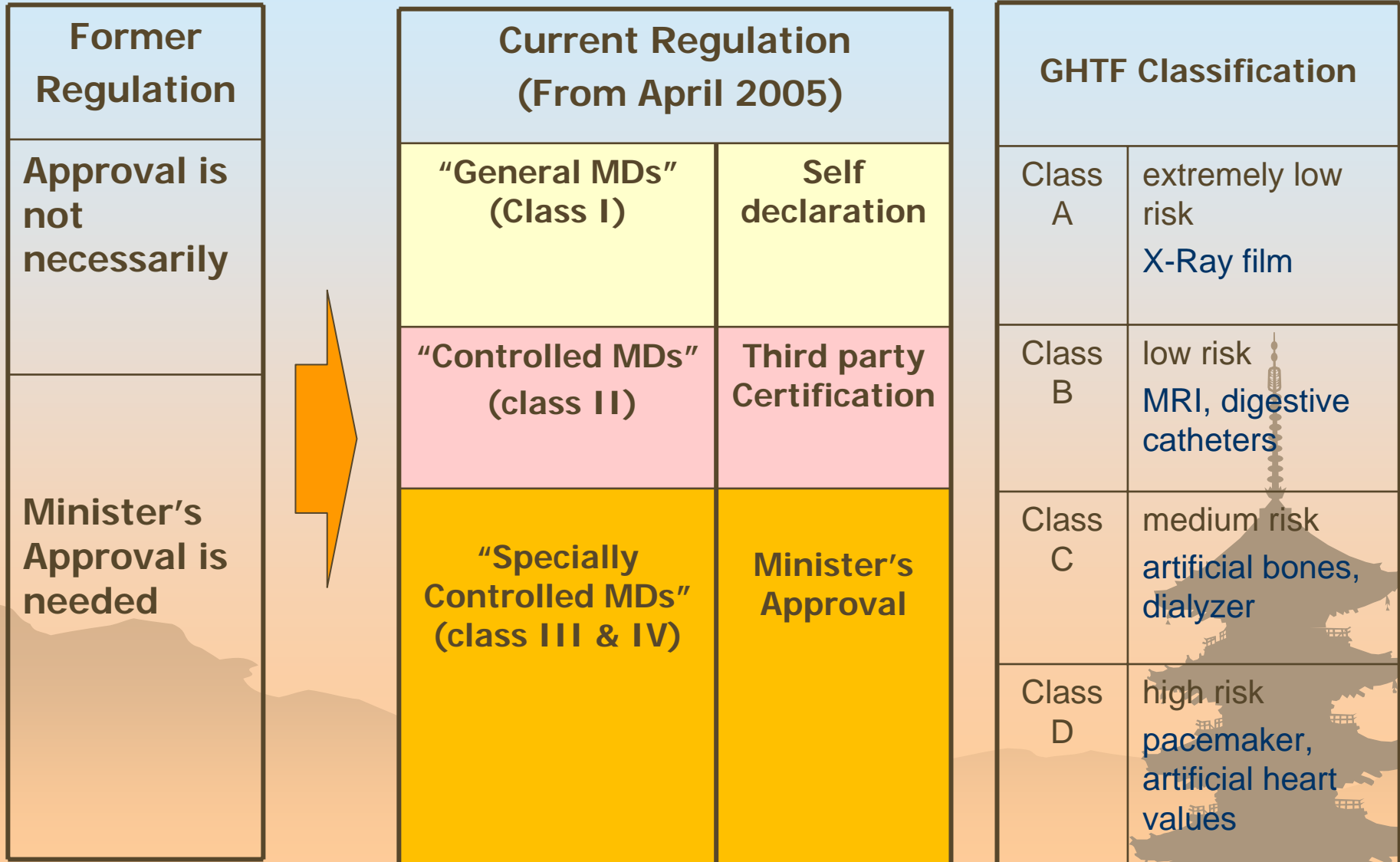


# Case 1 : MD classification

- ❁ Because one of the purpose of PAL revision 2002 was to establish risk-based MD regulation, it was good opportunity to introduce GHTF MD classification into PAL.
- ❁ With full cooperation of industry, we sorted out thousand of MDs into four classes. It was laborious but we've done it within 2 years after the publication of the revised law.



# Classification of Medical Devices



# Case 1 : MD classification(cont.)

## ❁ (barrier, problems)

Much effort in both of industry and regulator was needed.

Small groups of MDs were classified higher class by the GHTF rule and subject to more strict regulation compared to before.

## ❁ (benefit)

This was a first step for multilateral harmonization. It is expected that it provides fundamentals for fast access to foreign market in future.



# Case 2 : The Essential Principles

- The Essential Principles (EPs) were new requirement for Japanese industry and it was big challenge especially for small and medium companies. Therefore we took two step approach. Until April 2008, only “the General Requirements” are required. Then, “the Design and Manufacturing Requirements” will become obligatory.
- Industry has drafted around 400 checklists for conformity to EPs for class II (GHTF class B) MDs, product by product. They also drafted 26 checklists for class III, IV (GHTF class C, D) MDs as well.
- **(barrier)** EPs were new requirements and big challenges especially for SMEs.
- **(benefit)** EPs provide clear requirements for MDs.



## Case 3 : STED

- ❁ In Japan, application for approval should be filed with 1)Application form (*Shinseisyo*), 2)Summary of the products (*Shiryo-gaiyo*) and 3)Attachment (data sub set).

The Summary is quite useful in a review process because it is not only a compilation of data but also an applicant's view on how the data support safety and performance of the device.

- ❁ February 2002, STED(PD) was introduced on a trial basis for new or improved MDs. Applicant might use STED as the Summary.

- ❁ From 2005, STED(PD) has been used mandatory for application.



## Case 3 : STED (cont.)

**(barrier)** Many of Applicants are not accustomed to make and use STED. (eg. way of description)

**(benefit)** It is expected that it provide fundamentals for fast access to foreign market in future.

**(problem)** Should Japanese STED be changed following the revised STED?

→ STED currently used in Japan corresponds basically with the latest draft.



# Case 4: Combination products

- ❁ No specific definition for combination products in legal matter so far in Japan. We have managed to categorize them into drug or MD. (eg. Drug-eluting stents → MD, Prefilled syringes → drug)  
MD regulations apply to a combination product regarded as MD.
  - ❁ GHTF discussion on combination products is under way. No harmonized document at present.
  - ❁ It could be true that introduction of GHTF document is easier when there is no historical, consistent and robust regulation in the jurisdiction.
- Japan is paying close attention the combination products *Ad hoc*. Because the document it will develop could affect Japanese legislation.



# The way forward

- ❁ We should continue our effort to introduce harmonized GHTF documents into our regulations for conversion which decreases cost of gaining regulatory compliance and allows patients earlier access to new technologies and treatments.
- ❁ The effort increases importance of GHTF activity and the benefit from introduction of the GHTF documents further.

No pain, No Gain  
We need action to move forward.  
We should do what we can.

**Thank you!**

