

What Marketing Authorization Holders are Looking for in Foreign Manufacturers

For a Stable Supply

Briefing on the Pharmaceutical Affairs Law CPhI Japan 2013

April 25, 2013

Japan Generic Medicines Association
Quality Committee

The Japan Generic Medicines Association (JGA)

The JGA is an industry association with 41 member companies which manufacture mainly generic drugs within Japan, and eight associate member companies

The JGA works on improving the reliability of generic drugs

15 permanent committees with various special projects

Reliability improvement projects

Oriented towards encouraging the use of generic drugs

Stable supply

Quality securement

Information providing

Stable Supply of APIs

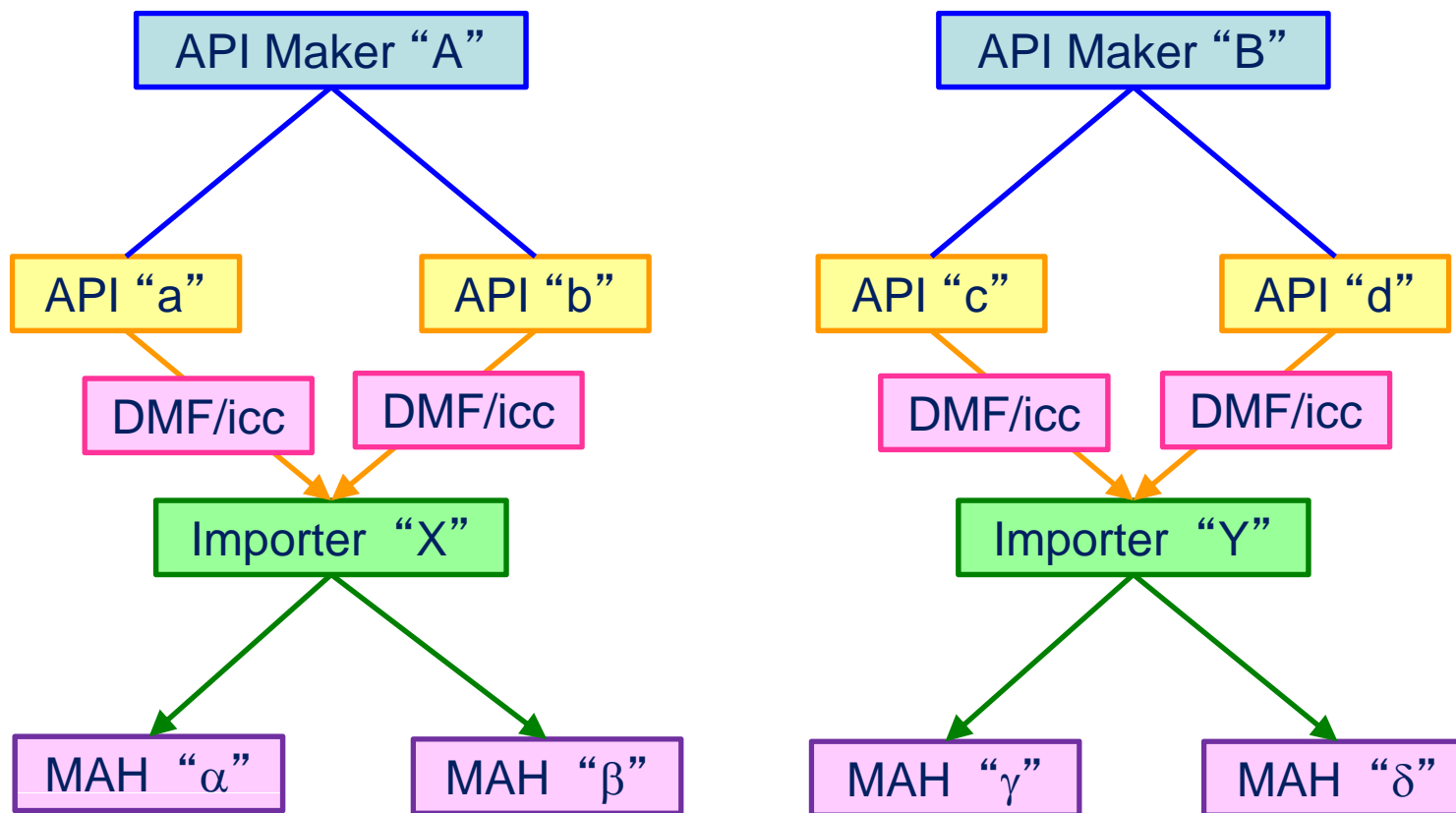
Issues of Non-compliance in GMP Compliance Inspections of Foreign Manufacturing Sites by the PMDA

Last year, the results of the PMDA's on-site inspections found there to be a series of cases of non-compliance, resulting in difficulties in exporting to Japan.

Shipments of a total of seven components, including four types of APIs and three types of important intermediate products manufactured by the relevant sites, were stopped.

A total of 14 companies were subject to administrative measures from the Ministry of Health, Labour and Welfare, and the supply of many generic drugs was stopped.

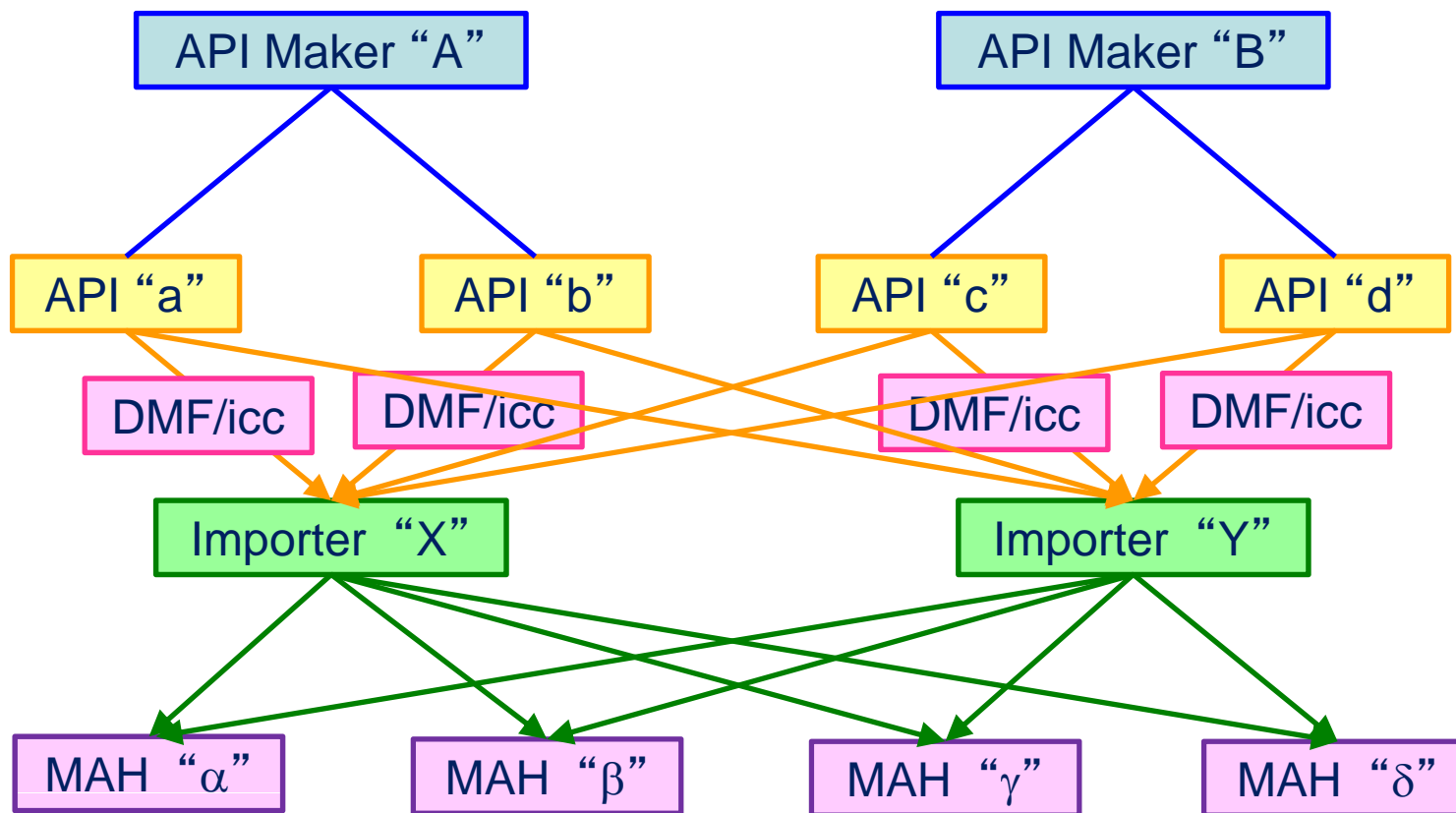
Stable Supply of APIs



DMF/icc : Drag Master File / in-country caretaker

MAH : Marketing Authorization Holder

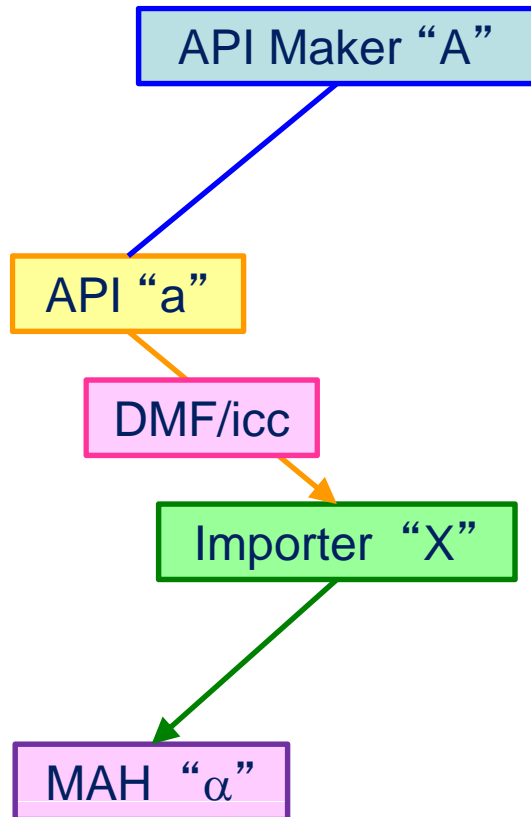
Stable Supply of APIs



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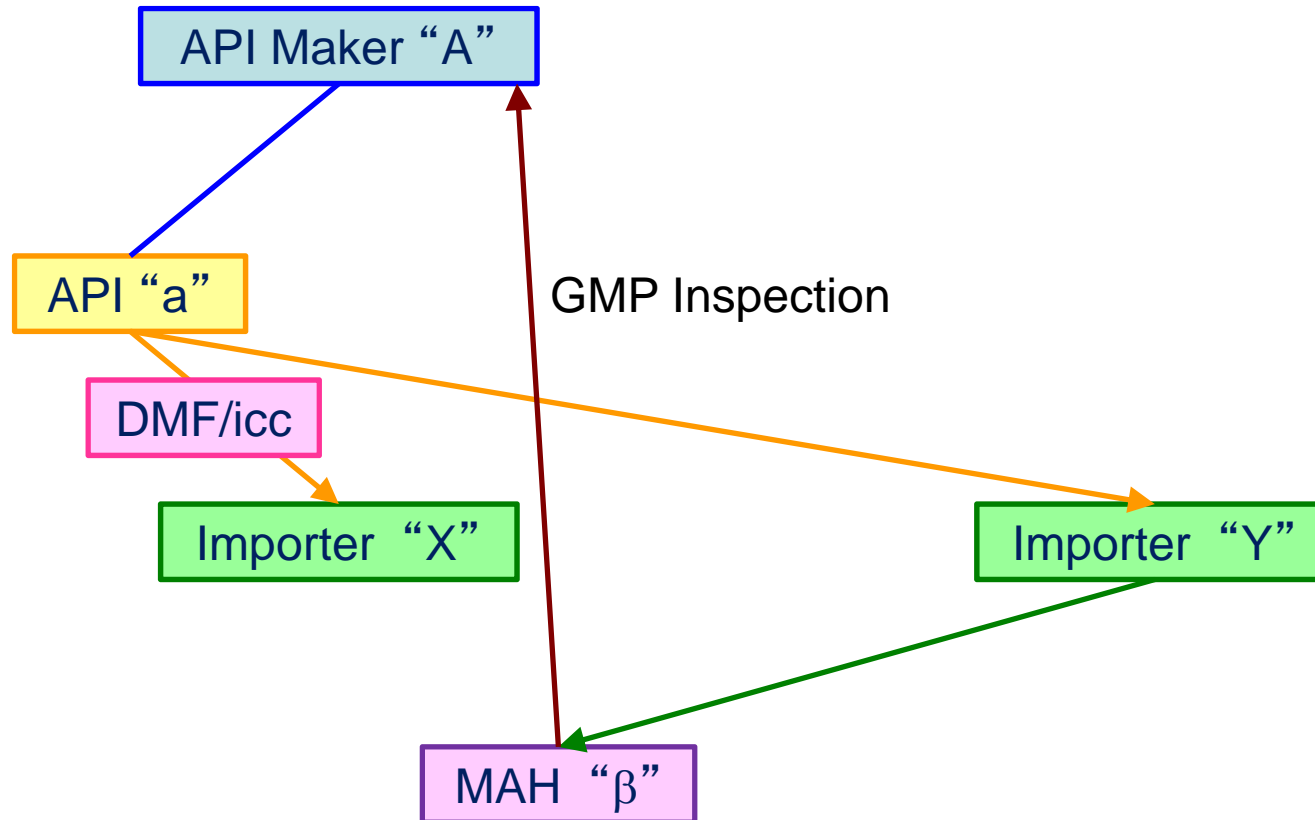
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Stable Supply of APIs

Role of In-country Caretakers of DMFs

To act as a neutral third party on behalf of foreign manufacturers through the PMDA's review of DMFs, in order to protect their intellectual property

To inform MAHs of planned/actual changes at foreign manufacturers

To assist the PMDA with GMP compliance inspections of foreign manufacturers

Stable Supply of APIs

Given the Roles of In-country Caretakers of DMFs:

We expect MAHs to select in-country caretakers of DMFs with certain **qualifications.**

We expect foreign manufacturers to pay attention to the **qualifications of in-country caretakers of DMFs.**

**We look forward to your support
in ensuring a stable supply
of high quality APIs**

<http://www.jga.gr.jp/>

Thank you for your attention

