Progress of New Drugs Working Group

藥求安全　食在安心

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Ministry of Health and Welfare

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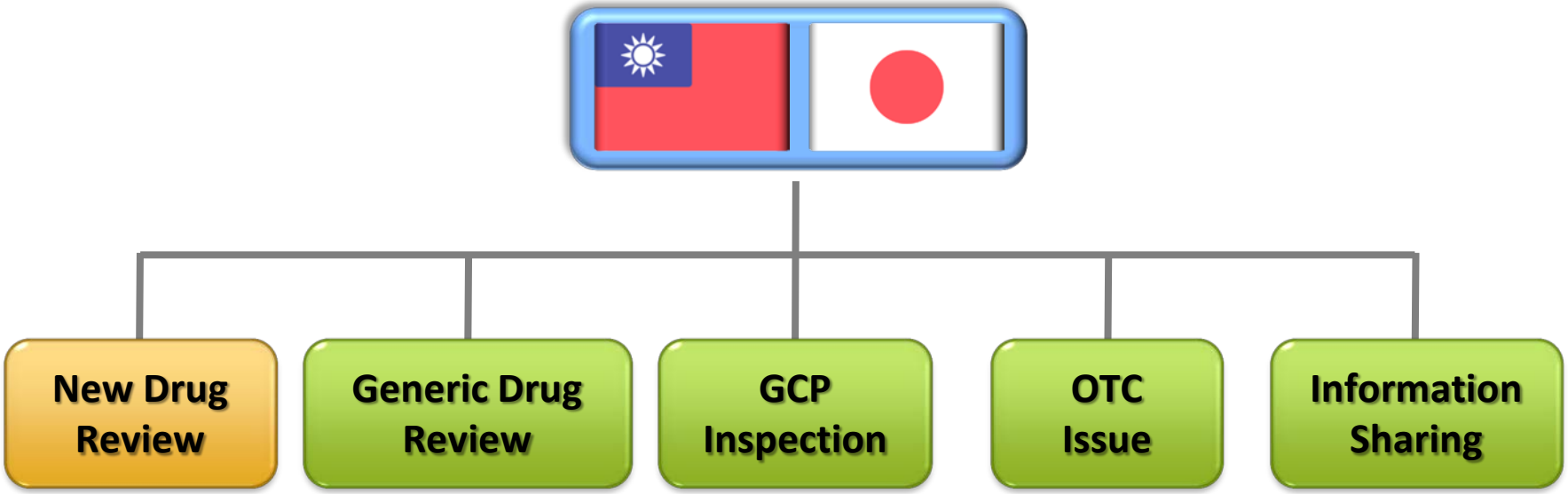
衛生福利部食品藥物管理署

Food and Drug Administration,
Ministry of Health and Welfare

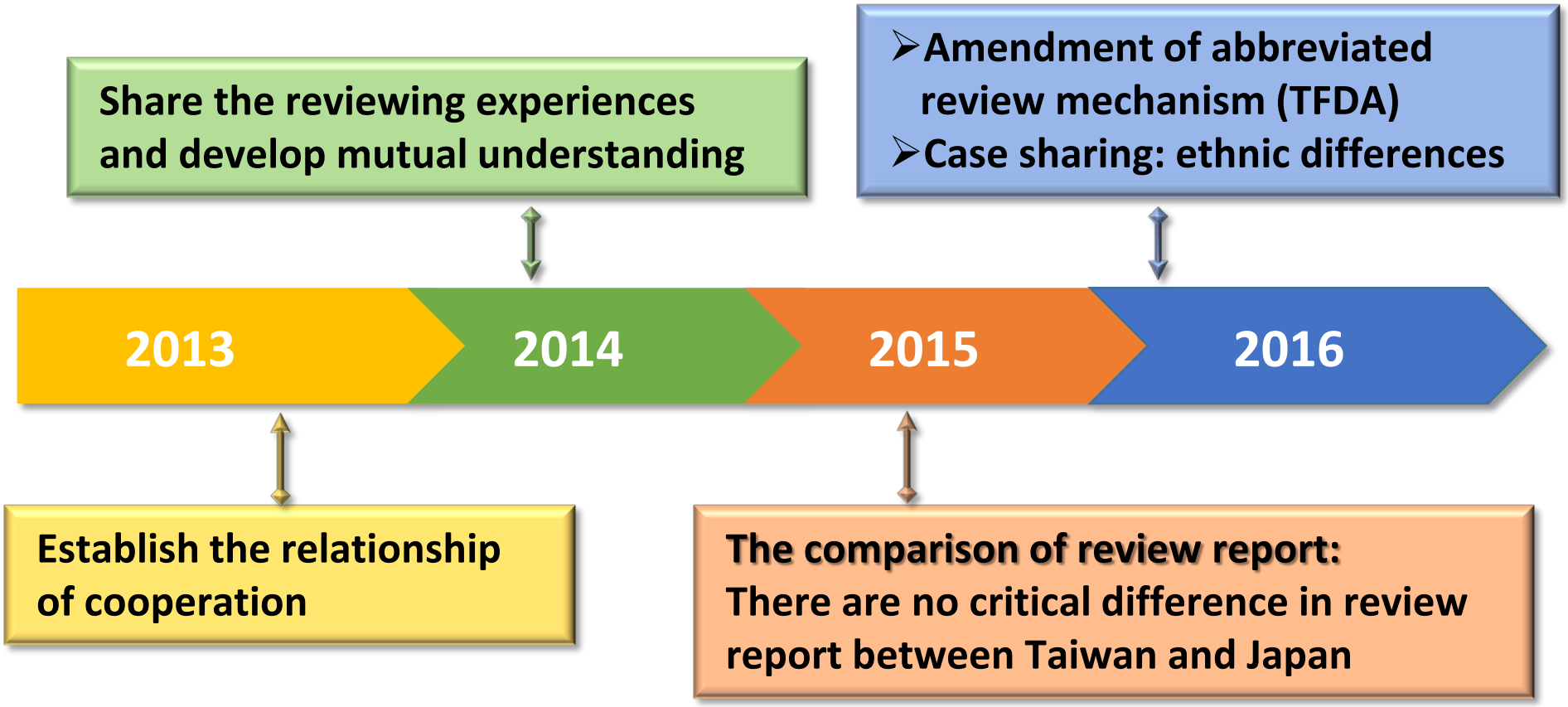
http://www.fda.gov.tw/

Working Groups (WG)

The collaboration between Taiwan and Japan since 2013



The Progress of New Drugs WG



Abbreviated Review Mechanism

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2011.03.01
Announcement

2016.07.28
Revised

Criteria

- ✓ **NCE with no ethnics difference**
- ✓ **Approved by two of three regulators including US FDA, EMA and MHLW/PMDA**

Advantage

- ✓ **Shorten the review time (180 days)**
- ✓ **Accelerate the drug availability and accessibility**

Case Sharing

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Purpose

Discussion of drug responsiveness in Asian populations using products approved at different doses in the US, EU, and Japan.

Optimization of drug development in East Asian may be required if there is major ethnic difference resulting in different dose regimen.

For confirmatory trial in some therapeutic categories, such as CV Study, large sample size is required to demonstrate statistically significant efficacy results.

East Asian confirmatory phase III studies , enrolling subjects from Taiwan, Japan ….etc. to facilitate drug development.

Future Plan

Confidential agreement (CA)

Case sharing & personnel exchange

Joint-review

Thank You for Your Attention

For more information

Website is at: http://www.fda.gov.tw