

Update on JP-TW Generic Drugs WG

4th Joint Conference of Taiwan and Japan on Medical Products Regulation
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Objective

The Objective of JP-TW Generic Drugs WG is

- to improve mutual understanding on generic drugs regulation and regulatory environment with regard to generic drugs in Japan and Taiwan

Past discussion

1st Meeting (2013)

- Comparison on Generic drugs review system
- Possibility on mutual utilization

2nd Meeting (2014)

- TW request: Mutual acceptance on data of BE study

3rd Meeting (2015)

- Pending discussion until outcome prepared by JP Scientific Research

Before 4th Meeting (2016)

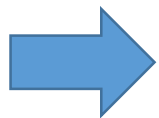
- No WGs held

JP Scientific Research (FY 2015)

[Research]

- Administration condition of oral solid form BE study
- Judgment of solution study
- Data acceptance of BE study conducted in Foreign countries

And so on



[Current Result]

Need more discussion in the JP Scientific
Research in FY 2016

Future consideration

1. Mutual acceptance on data of BE study (*continuous discussion*)
2. Comparison study on generic drugs review by Taiwan and Japan (Update)
3. Collaboration by Taiwan and Japan to international regulatory convergence activity of generic drugs

Thank you very much!!



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