

## Notes on consultation and implementation in the three ICH Regions

### EU

The ICH Guidelines are submitted to the Committee for Human Medicinal Products (CHMP) for endorsement once they have reached *Step 2* or *Step 4* of the ICH Process. The CHMP, in consultation with the European Commission decides on the duration for consultation with interested parties (up to 6 months).

The European Agency for the Evaluation of Medicinal Products publishes and distributes the *Step 2* Guidelines for comments. At *Step 4* the Guidelines are endorsed by the CHMP and a timeframe for implementation is established (usually 6 months).

The Guidelines are subsequently published by the European Commission in the Rules Governing Medicinal Products in the European Union.

*Step 2* and *Step 4* Guidelines are available on the European Medicines Agency (EMA) website

### MHLW

When *Step 2* or *Step 4* has been reached, the ICH texts are translated into Japanese. Subsequently Pharmaceutical and Medical Safety Bureau (PMSB) notification for the promulgation or consultation of Guidelines written in Japanese is issued with a deadline for comments in the case of consultation drafts, or an implementation date for finalised Guidelines. The notifications on Guidelines in Japanese and also English attachments (ICH Texts) are available from PMSB or on the Pharmaceutical and Medical Devices Agency (PMDA) website.

### FDA

When *Step 2* or *Step 4* has been reached, FDA publishes a notice with the full text of the guidance in the Federal Register. Notices for *Step 2* guidances include a date for receipt of written comment; *Step 4* guidances are available for use on the date they are published in the Federal Register. FDA guidances and Guidelines are available on the FDA website.