Notes on consultation and implementation in the 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/PMDA
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.

Health Canada
Consistent with the ICH guidance development process, Health Canada posts draft guidances (Step 2) on its website and solicits comments. Comments received are forwarded to the relevant ICH working group for consideration in the finalisation of the guidance. The coming into effect of finalised (Step 4) guidances by Health Canada may at times be affected by the need to undertake certain activities including collateral guidance and policy work, training, staffing, business process changes and/or a regulatory amendment. Health Canada adopts ICH guidances once routine administrative steps have been completed and posts final guidances on its website. In exceptional situations where an effective date cannot be established at the time of adoption and publication by Health Canada, an explanatory statement to this effect will be included in the covering notice and the title page of the guidance published on Health Canada’s website.