

ICH Q11 IWG Work Plan

24 March 2017

Topic Adopted: November 2014

Last Face-to-Face Meeting: Lisbon, Portugal - June 2016

1. Anticipated Milestones

Completion Date	Deliverable
November 2017	<i>Step 4</i> Q&A document

2. Timelines

Date	Task / Activity	Details
June 13-16, 2016	Face-to-face meeting (Lisbon, Portugal)	➤ Completed a draft Q&A document for Constituent review
June 20, 2016 - August 15, 2016	Constituent review of draft Q&A document	➤ Constituency review with a template for providing and collating comments
August 15, 2016 - October 13, 2016	IWG review of comments and updating of Q&A document	<ul style="list-style-type: none"> ➤ Applied the previously used Regional team approach to advance work (e.g., IWG representatives worked in Regional clusters). Distributed questions based on relevance and source of the feedback received ➤ Regional teams reviewed the feedback and developed updated wording for the assigned Q&As ➤ IWG increased the frequency of teleconference calls (initially at every 2 weeks, October was weekly) ➤ Assessed and edited all Q&As based on constituents feedback
October 27, 2016	Sign off of <i>Step 1</i> document	➤ The full IWG (experts of all Members, Observers, and Other Participants) signed off the <i>Step 1</i> document.
November 2016	Deliver a consensus <i>Step 1</i> document to ICH Assembly/MC	➤ Received endorsement by the ICH Assembly/MC during Osaka meeting for proceeding to <i>Step 2a/2b</i>
December 2016 to April 2017	Public consultation on the <i>Step 2b</i> document (start of <i>Step 3</i> in ICH process)	<ul style="list-style-type: none"> ➤ Public consultations timelines (close date): <ul style="list-style-type: none"> ○ ANVISA: 16 Feb ○ MHLW/PMDA: 12 March ○ ICH: 15 March

		<ul style="list-style-type: none"> ○ EU: 15 March ○ HC: 15 March ○ Swissmedic: 15 March ○ FDA: 23 March ○ MFDS: 13 April
April/May 2017	<p>Regional review and prioritisation of comments received in public consultation. Sharing the output of regional review with IWG.</p> <p>IWG Telecons scheduled through April & May</p>	<ul style="list-style-type: none"> ➤ Parties in each region to convene in order to review the comments received from the consultation using a common template. ➤ To conduct a first review of comments and prioritise for discussion in full IWG. ➤ All comments to be retained for transparency. ➤ Regions will share the output of the reviews with the IWG by 15 May.
May/June 2017	Face to face meeting (Montreal)	<ul style="list-style-type: none"> ➤ F2F meeting (see Section 4) to discuss and live edit the document based on public comments and regional review. ➤ Goal to reach pre-Step 4 document for final constituency review.
October 2017	Finalisation of the Question & Answer Document	<ul style="list-style-type: none"> ➤ IWG to meet by tele/web-conference to consider any significant comments arising from constituency review. ➤ IWG to have reached agreement on the Step 3 Experts Draft Guideline for sign off by experts.
November 2017	<i>Step 4</i>	➤ Targeting a <i>Step 4</i> document