

## **Remit of the Informal Generic Drug Discussion Group**

*Endorsed by the ICH Management Committee on 30 January 2019*

### **General Description**

The Informal Generic Drug Discussion Group (IGDG) will serve as a technical discussion group for issues relevant to harmonisation of scientific and technical standards for generic drugs. The IGDG will recommend areas for harmonisation under ICH and assess feasibility of harmonisation of various topic areas within existing regional regulatory frameworks.

The IGDG will operate in line with the applicable ICH procedures, similar to other ICH Technical/Discussion Groups, under the oversight of the ICH Management Committee (MC), with reporting to the ICH Assembly. As the remit of ICH is to harmonise technical standards, the IGDG should in its work remain focused on technical and scientific issues. Matters related to statutory and regulatory parameters are strictly beyond the scope of the remit of this IGDG; these matters fall under the remit of the regulatory authorities in different jurisdictions.

### **Duration of Tenure**

The discussion group (DG) will serve for a period of one-year. Thereafter, the MC will consider whether this DG should sunset or whether additional work merits its continuation for another specified term.

### **Scope of Activities**

- Identification of specifically recommended new topics for harmonisation under ICH that are deemed highest priority in the near term
- Review any ICH topic proposals related to standards for generic drugs and make recommendations for any revisions or resequencing of work, as needed and requested by the ICH MC
- Survey of existing ICH Efficacy and Multidisciplinary guidelines as well as relevant WHO guidelines related to generic drug standards to assess for any gaps in guidance for generic drugs
- Recommended prioritization of other topic areas for future generic drug-related harmonisation work under ICH

**The Informal Generic Drug Discussion Group should endeavour to complete the following activities within the initial one-year term:**

- Review any ICH topic proposals related to standards for generic drugs and make recommendations for any revisions or resequencing of work, as needed and requested by the ICH Management Committee
- Identify priority topic areas for harmonisation under ICH that would present public health benefit and would be feasible for harmonisation given existing regional regulatory frameworks.

- The DG will serve to identify converging views around areas that would be viewed as valuable harmonisation projects for generic drug standards that could be undertaken in the near term
- A single party would volunteer to submit the topic proposal(s) through the annual topics process for the Assembly's consideration
- Conduct a survey of existing ICH Efficacy and Multidisciplinary Guidelines to assess any gaps in guidance for generic drugs and make recommendations for revisions to existing ICH guidelines. Additionally, relevant WHO guidelines related to generic drug standards should be reviewed to align guidance and avoid duplication of effort where appropriate.
  - The DG should collaborate with the Informal Quality Discussion Group, as appropriate, in assessment of existing Quality guidelines.
- Recommend a prioritization for harmonisation work for standards for generic drugs including any sequencing of new topics and revision of existing guidelines.

### **Type of Expertise Needed and Resources**

The IGDDG should be comprised of a diverse group of strategically-oriented experts that collectively have extensive knowledge of the scientific and regulatory aspects related to bioequivalence, pharmacokinetics (PK), PK study design, biostatistical methods for bioequivalence evaluation, biopharmaceutics, and in vitro dissolution.

It is envisioned that the IGDDG should be comprised of experts from Members and Observers of the ICH Assembly, in accordance with the applicable Articles of Association, Rules of Procedure, and Standard Operating Procedures. ICH Members and Observers participating in the IGDDG should be allowed to nominate standing experts and alternate experts to enable an appropriate balance of expertise while keeping the size of the IGDDG manageable, in accordance with the applicable Standard Operating Procedures.

### **Operating Model and Term**

The IGDDG should complete its activities in a virtual setting via email and teleconference. In exceptional cases, the ICH Management Committee (MC) may consider granting a face-to-face meeting of the IGDDG during a biannual ICH Meeting upon approval of a specific work plan in line with current practice for other ICH Working Groups.

The leadership of the IGDDG should be comprised of a Rapporteur and a Regulatory Chair, in accordance with the applicable Standard Operating Procedures.

The IGDDG will operate for a 1-year term beginning on the date --following the approval of the IGDDG remit by the ICH MC-- when the membership of the IGDDG is confirmed. The IGDDG should provide an update of its activities and progress to the ICH MC within 3 months after its initiation and then update at least biannually (or more frequently upon request) to the ICH MC and the ICH Assembly, in line with current practice for other ICH Working Groups. At the end of the initial 1-year term, the ICH MC will consider whether to grant an extended term to the IGDDG.

**Potential Timeline for Specific Tasks\***

<b>Expected future completion date</b>	<b>Milestone</b>
<b>Month 1</b>	Initial call to discuss the DG work plan
<b>Month 2 – 3</b>	Discuss and review any ICH topic proposal(s) related to standards for generic drugs, if needed and requested by the ICH MC
<b>Month 4</b>	Review existing WHO guidelines
<b>Month 4 or 5</b>	T-con with the ICH Informal Quality Discussion Group (IQDG)
<b>Month 5 – 7</b>	Identify priority guidelines or guideline series on recommended areas for harmonisation on standards for demonstrating BE
<b>Month 8 – 9</b>	Review existing ICH Efficacy and Multidisciplinary Guidelines to assess a need for revision to add additional guidance for considerations for generic drug standards
<b>Month 10</b>	Finalize DG recommendation on any proposed revisions to ICH Guidelines
<b>Month 11 – 12</b>	DG finalizes overall recommendations and prioritizes work areas

\*Note: The IGDG will review this timeline once established and consider whether any modification is necessary to optimize the timing and sequencing of events e.g. teleconference with the IQDG.