Final endorsed Business Plan
M9: Biopharmaceutics Classification System-based Biowaivers
7 October 2016

1. The issue and its costs

- *What problem/issue is the proposal expected to tackle?*

  From current regulatory guidelines/draft guidance which includes the possibility of Biopharmaceutics Classification System (BCS) based biowaivers, it appears that BCS based biowaivers may not be recognized or that the requested supportive data for such applications differs. In addition, even the classification itself may differ. This means that pharmaceutical companies have to follow different approaches in the different regions. This lack of harmonisation may imply that additional bioequivalence studies should be carried out, depending on the region/guideline. Furthermore it may hamper a streamlined global drug development.

- *What are the costs (social/health and financial) to our stakeholders associated with the current situation or associated with "non action"?*

  The conflicting regional recommendations on the acceptability of BCS based biowaiver are leading to different requirements and possible the need of *in vivo* data (bioequivalence study) instead of *in vitro* studies (dissolution data). This results in increased drug development costs overall and sometimes to unnecessary exposure of healthy volunteers to medicinal products.

2. Planning

- *What are the main deliverables?*

  The main deliverable is a guideline document on BCS-based biowaivers, which provides clear requirements on the applicability of BCS-based biowaivers and on supportive data for such application.

- *What resources (financial and human) would be required?*

  It is anticipated that the *Step2 a/b* document will be approximately completed in 1 - 2Q 2018. It is envisaged that a WG member needs 18 - 24 days/year to work on the development of this guideline.

- *What is the time frame of the project and what will be the key milestones?*

  The request will be submitted to the ICH Management Committee (MC) in September 2016 with expectation of the EWG meeting face-to-face in November 2016 at Osaka.

  It is anticipated that the *Step2 a/b* document will be completed in 1 - 2Q 2018 and that *Step 4* will be reached in 2Q 2019.

3. The impacts of the project

- *What are the likely benefits (social, health and financial) to our key stakeholders of the fulfilment of the objective?*

  Clarifying the basic requirements for accepting and applying BCS-based biowaivers by establishing a guideline, reduces the need for carrying out additional clinical (bioequivalence) studies in humans. As a result, international harmonisation on the topic can accelerate the development of new drugs, line extensions of new drugs and generics and can lower the costs significantly.

- *What are the regulatory implications of the proposed work – is the topic feasible (implementable) from a regulatory standpoint?*

  The proposal is consistent with current laws and regulations of the ICH regions. Regulatory authorities responsible for reviewing pharmacokinetic (bioequivalence) data will need to agree globally on accepting and applying BCS-based biowaivers. This guideline will supersede regional guidelines, and mutual use of the data in different countries/regions based on the guideline will become possible.

4. Post-hoc evaluation

- *How and when will the results of the work be evaluated?*

  In case scientific data become available which may support the classification of other BCS classes as mentioned in the guideline, or in case supportive data become available resulting in a change of the requirements of BCS based biowaivers, after the topic reaches *Step 5* in each region, the EWG may need to evaluate/update the guideline, if any.