PMC Processes

1. Introduction

During the past months, the Secretariat identified the need to clarify some of the PMC processes to ensure that the last part of the race to May 2018 will be as smooth as possible. Please find here below a summary of the roles and actions needed from the companies in this context split into three main steps.



2. Time to input

Companies are members of different work groups and task forces. Several meetings, conference calls but also email exchanges have been and will still be organized to discuss the technical strategies and issues (e.g. read-across approach, derivation of PNECs and DNELs, development of exposure scenarios). The main input on a content point-of-view must be provided via these different exchange platforms. The biannual Back-to-Back meetings of the Work Groups are a critical occasion to review and discuss more holistically some of these technical decisions.

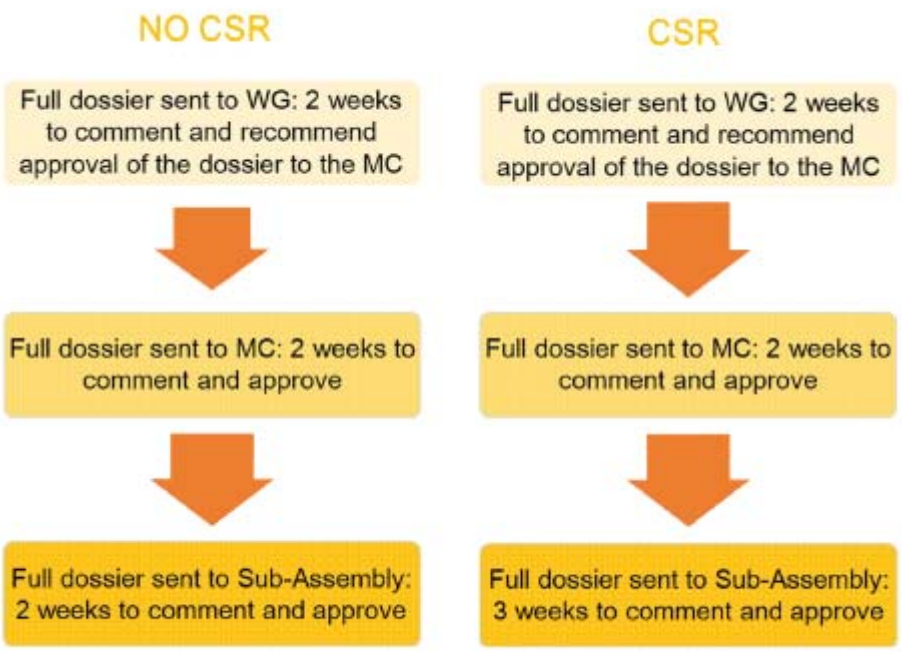
During this period, critical decisions must be taken and this is always done by consensus. However, some of the decisions could be extremely urgent and especially in the context of animal testing. It is therefore proposed that for urgent decisions related to animal welfare during mammalian testing, some of the decisions can be taken by the Secretariat with the support of a limited number of agreed tox experts (see process description in annex 1).

3. Time to approve

When a dossier is finalised, there is a formal approval process foreseen in the PMC agreement involving the different levels of recommendation/decisions: the relevant Work Group, the Management Committee and the relevant Sub-Assembly.

At the Assembly meeting of June 2016, the following procedures for this approval process have been approved: the standard procedure and a fast-track procedure.

1. The standard procedure



2. The fast-track procedure

Procedure applicable if only one registrant (at Work Group and Sub-Assembly), or in case of Annex III exempted dossier (only phys-chem data required):

- if only one registrant: only the approval of this member is requested
- if Annex III exempted dossier: only one step for the approval with ONE SENDING to relevant Work Group, Management Committee and relevant Sub-Assembly with a period of 2 weeks for approval.

It is worth to note that during this approval process, no major changes can be taken into account but only corrections or minor comments in line with the overall strategy.

4. Time to act

After the approval of the registration dossiers by the relevant body/ies, this is the time to act for Lead Registrants and co-registrants. Each Lead Registrant received an indicative timesheet to help to organize themselves and split the work. The Secretariat tries to keep these sheets up to date based on the latest developments which could influence the submission (date) of the registration dossier. It is critical that Lead Registrants respect the agreed timeline to ensure that co-registrants have time enough to submit their individual dossiers. Moreover, due diligence in the LR submission will allow splitting the workload and avoid that all the submissions must be done at the same time.

Annex I: Urgent decisions for animal wellfare - process

1. The testing lab is requested to immediately alert the study monitor(s).
2. The study monitor(s) must directly contact Jelle Mertens and France Capon by SMS to avoid losing time.
3. The Secretariat contacts the three mandated experts by email/SMS/phone to ensure a quick decision.
4. A decision is taken as soon as one of the experts replies, and communicated directly to the testing lab via the study monitor (s).
5. The relevant Work Group is informed afterwards via email on the decision taken.