eCTD and renewal submission FAQs

1. **What is the eCTD baseline submission?**

   The term (eCTD baseline submission) refers to submission of the already approved dossier that was submitted and approved by PDCD in other format; in other words, it is the conversion from CTD to eCTD. It is worthy to mention that the baseline submission always takes the sequence 0000.

2. **What are the components of eCTD baseline submission?**

   Pharmaceutical industries are encouraged to submit all modules (1 – 5) whenever applicable. If the full file is not available, at least module 1 & 3 should be submitted as per GCC guidelines for eCTD baseline submission.

3. **What hard documents needed to be submitted with eCTD baseline submission?**

   The cover letter is the only document needed to be submitted with the baseline.

4. **Can renewal file be submitted as the eCTD baseline submission?**

   Yes, it is accepted to submit the renewal file as baseline. The company shall submit all modules (1 -5) if available. If not, all module 1 documents required for renewal (as per mentioned in *Data Requirements for Renewal* guidelines) should be submitted along with full module 3

5. **Can variation be submitted with the renewal file?**

   Yes, variations can be submitted within the renewal file with the conditions of clarifying that in the cover letter and submitting a clear comparison table showing the variations exactly.

6. **Can the agent submit the renewal file while there is still a variation file pending at PDCD?**

   No, you are not allowed to submit the renewal file until the variation file is approved (the regulatory activity is closed). Then, you can submit the renewal file

7. **As per circular 13/2019, I can still submit files in CTD format till 1st Sep 2020, is this applying for renewal files as well?**

No, this grace period is applied for new registration files as well as variation files. Renewal files should be submitted in eCTD format only.

8. **Circular 12/ 2019 on lab analysis gives us the option of submitting either a quantity enough to cover full analysis OR as per the recommended minimum sample size defined in the table in the circular. If the company believes that the quantity enough to cover full analysis is less than that defined in the table of the circular, will this be accepted by MOPH?**

   No, the numbers mentioned in the table are the minimum that should be submitted for analysis.

9. **Regarding the approved products that are not prone to renewal for the next 2 years (registered at 2015 and beyond), when should I submit the baseline? Should I wait for a variation application to submit the baseline, or can I submit it separately without waiting for the next variation?**

   You can submit the baseline starting from 1st Sep 2019 without waiting for the next variation.

10. **After submitting the eCTD baseline, can I submit any request in CTD format?**

    No, once the company submitted the baseline, they should follow eCTD structure in any further submission

11. **Regarding the products that should be renewed the next 2 years (registered in 2013 & 2014), can I wait till they expire in 2020 and submit the renewal file?**

    All the agents are requested to submit the renewal files for these products starting from 1st Sep 2019 and during the period of 2 years. Each agent should submit specific number of renewal files as per PDCD plan.

12. **Appendix 2 "cover letter" in eCTD submission guidance, will it be prepared by MAH or agent or both?**
    Both the agent and company should prepare the letter. For the cover letter submitted from the agent, it should be original, signed and stamped.

13. **What is the maximum limit for the number of renewal applications?**

    That depends on the agent and how many registered products you have. Each agent is notified with his/her limit by email.

14. What is the timeline for approval of renewal file?

This depends on many factors. We confirm that we planned to finalize in very short period