



INTRODUCTION OF “PRE-SUBMISSION MEETINGS” FOR SUBMISSION OF CTD DOSSIERS FOR LOCALLY MANUFACTURED PHARMACEUTICAL PRODUCTS.

The management of NAFDAC has noticed with dismay the high number of dossier applications that do not meet minimal requirements for submission of CTD dossiers.

As part of its continuous improvement efforts and strengthening of its regulatory systems, NAFDAC is introducing a ‘pre-submission meeting’ applicable only to local pharmaceutical manufacturers to enhance the quality of dossiers submitted by them. The goal is to create an opportunity for intending applicants to engage with the dossier review team to address pertinent queries and clarifications regarding the minimal requirements for CTD Dossier submission.

The meeting will avail the local pharmaceutical manufacturers the opportunity to bring up their concerns and challenges while our team provides guidance on NAFDAC expectations and way forward regarding CTD dossier submission for registration of locally manufactured pharmaceutical products. This is expected to help reduce the number of dossier applications that get rejected on submission.

Considering the limited number of staff available to handle this task as against the number of local pharmaceutical manufacturing companies, management has decided that the meetings would be virtual and would be limited to one application per product line per company.

It is our hope that the knowledge gained from discussions on such product dossiers would be useful in preparing similar dossiers for other products on the same line.

Priority would be given to new companies who may be inexperienced in the expected norms and standards regarding CTD dossier submission.

Please note that applicants are expected to submit the filled QOS (quality overall summary) for the product to be discussed to the dossier review team at least one week ahead of the scheduled pre-submission meeting. This will enable adequate preparation and judicious use of available time by the dossier review team.

The Pre-submission meetings will be effective from 2nd of January, 2024.

Thank you.

Prof. Mojisola Christianah Adeyeye, FAS
Director General - NAFDAC