

NOTICE

Date: 28.01.2015

Pre-submission Meetings - (*Regulatory Pathways*)

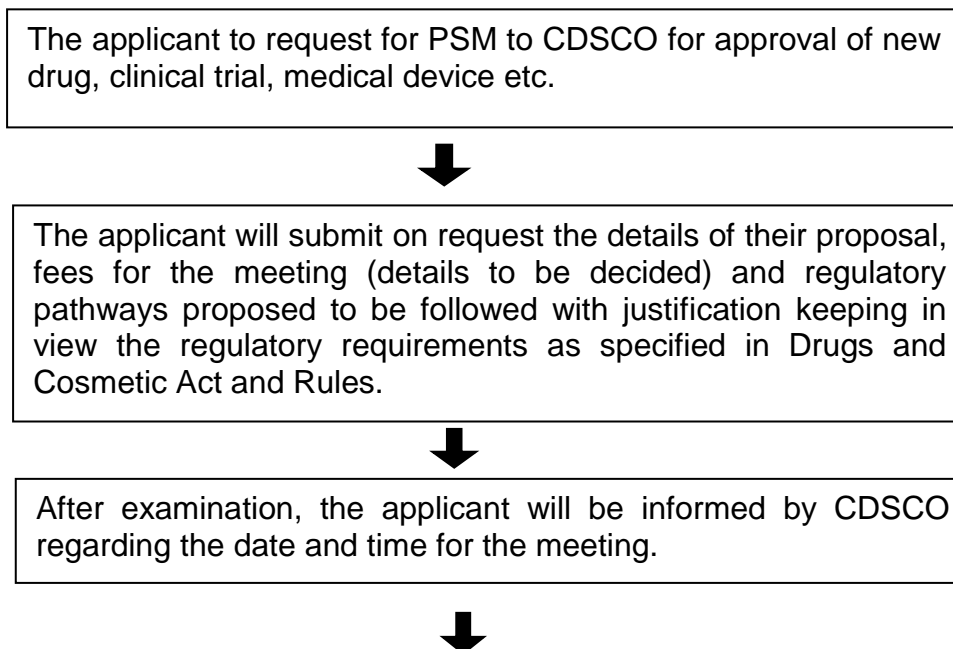
CDSCO has started pre-submission screening meetings few year back with stakeholders to bring out transparency and ease of disposal of the cases. This practice has been working successfully.

From time to time, the stakeholders are further pleading to create a window for technical deliberations between stakeholders and regulators. It is therefore decided to introduce a system of formal Pre-submission Meetings (PSM) of applicants with CDSCO officers and subject experts to discuss regulatory pathway in respect of specific application for approval of clinical trial, new drug, medical device etc.

The system will facilitate to understand the regulatory pathways required to be followed by the applicants for approvals resulting in bringing

- transparency
- accountability
- predictability and
- speedy disposal of cases

Steps (proposed)



During the meeting, the applicant shall make presentation of their proposal before the CDSCO officials and the subject



The detailed deliberation will be held with the applicant keeping in view the regulatory as well as scientific aspects relevant to the proposal.



The regulatory pathways in respect of specific application will be decided based on the presentation / information provided by the applicant.



The proceedings will be recorded and minutes prepared will be duly signed by the CDSCO officials, subject Experts and the applicants.



One copy of the minutes will be issued to the applicant for submission of their formal application and further action as per the agreed regulatory pathways.

Note:

- The principle of confidentiality will be maintained in such meetings.
- The agreed regulatory pathways in respect of any application will be specific to that application only and will not be applicable for any other applications of the same applicant or any other applicant.
- The PSM is not mandatory before submission of any application for approval of new drug, clinical trial and medical device etc. Applicant is free to submit such application even without any PSM.



All concerned are requested to give their suggestions in this regards to the office of Drugs Controller General India at dcg@nic.in by 9th Feb, 2015.