November 22, 2018

From

[redacted]

To

Therapeutic Goods Administration
Woden ACT 2606
Australia

Subject: Invitation to comment on public consultation - transition to accepting only eCTD formatted dossiers for prescription medicines. Email dated October 25, 2018

Dear Sir / Madam,

We, Biocon Limited have already been using [redacted] for eCTD, and have already submitted [redacted] with the TGA in eCTD format. Hence, the timelines given by the TGA for mandating only eCTD format for all of the three stages that are mentioned on pages 12-14 of "*Transition to eCTD only for prescription medicines*" (version 1.1, October 2018) are acceptable.

Further, all our regulatory submissions are copied in physical media (compact disc) and couriered to TGA currently. We request TGA to create an Electronic Submission Gateway (ESG) for accepting all regulatory submissions. Advantages of submission via Electronic submission gateway (ESG) are tabulated below;

Disadvantages of Regulatory Submission via Compact Disc (CD)	**Advantages of Regulatory Submission via Electronic Submission Gateway (ESG)**
As the CD containing Regulatory information (such as dossiers, ASMF, response to queries etc.) is couriered to TGA, there is delay in submission of the information.	The Regulatory information can be submitted by Pharmaceutical industries to TGA on-line. Thereby delay in transmission of information can be avoided.
There is no protection of data/information while submitting in CD as there is possibility of getting access to the CD by third party.	Data/information submitted via ESG is protected from third party access.
	Also, submission via ESG avoids courier expense.