

Biocon Statement on Parts of the Charge Sheet Leaked to a Media Outlet

Bengaluru, India: Aug 25, 2022

“It is unfortunate that parts of the charge sheet filed in the court have been leaked and some media outlets are carrying stories based on the same.”

Biocon has not received a copy of the chargesheet yet; hence we cannot comment further in detail.

Biocon would like to reiterate that:

“We follow global best practices in regulatory science which has earned us the distinction of being the only Indian company with the largest number of regulatory approvals for Biosimilars in ICH countries like USA, Canada, EU, Japan and ANZ amongst others.

“We have followed due process in seeking phase 3 waiver from DCGI for our biosimilar product Insulin Aspart, as per the current provisions and with precedence of the word ‘protocol’ used for such approvals. Insulin Aspart was approved by the EU and Canada respectively prior to the filing of an application before the Indian CDSCO and this is one of the considerations for the grant of an Indian Approval. Under the Indian Regulations, Indian Approval for a foreign approved drug is not an exception as surmised by the investigating agency and is in fact within the rules.

“The company has not made any payments to Bioinnovat Research or any other party named to facilitate the alleged bribe to the CDSCO official. We deny other allegations on wrong doings in seeking approval for Insulin Aspart under existing provisions and precedence. We reiterate our confidence in the judicial system and have fully cooperated with the investigating agency.”

-Company Spokesperson, Biocon Biologics

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