

GVK Bio refutes data manipulation in drug studies

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Recently, European Medicines Agency (EMA) in a statement said that four EU Member States have decided to suspend marketing authorizations of medicines authorized on the basis of studies conducted at the GVK Biosciences site in Hyderabad.

Refuting this, Mr Manni Kantipudi, CEO, GVK Bio, stated: "The regulatory authorities have themselves stated that, 'This decision is taken out of precaution. No element at this stage has led to establish a true risk for human health or a lack of efficacy of these drugs'.

We believe that the conclusions of the ANSM ((Agence Nationale de s curit  du m dicament et des produits de sant )) and the subsequent actions by the EMA are highly disproportionate to the actual risk posed to human health. At the same time, we respect and honor the conclusion made by the European regulators, and are working with our clinical development customers to provide new data that meets all regulatory requirements."