GVK Biosciences responds to DCGI's Letter on Clinical Trial of Wyeth's Investigational Vaccine

This refers to the media reports relating to the death of a child who was participating in a clinical trial of an investigational vaccine for the prevention of pneumococcal disease in which GVK Biosciences was associated as the CRO responsible for site monitoring.

GVK Biosciences has received and responded to a letter from the office of the Drug Controller General of India (DCGI) based on findings of a 2-person inspection team appointed by the regulator.

In its response, GVK Biosciences has clarified the following points:

- That the investigators conducting the trial at the site were trained on GCP-related topics on 4 separate occasions and each member of the team qualified an on-line GCP and Drug Safety module as required by the sponsor.
- That the Principal Investigator at this site had extensive experience of clinical trials, including vaccine studies.
- That all protocol and GCP requirements were followed by the site, and detailed documentation of the same was maintained in trial files that were not taken into consideration by the inspectors.
- That the inclusion of the subjects in the study followed the guidance given in the protocol as well as prevalent norms for vaccination recommended by professional bodies.
- That all norms of Good Clinical Practice were followed in the application of the informed consent process as well as for maintenance of accountability of investigational products.
- That an exhaustive Study Reference Manual provided to each site by the sponsor served a detailed Standard Operating Procedure that was strictly followed by the site throughout the course of the study.
- And that the study team applied particular care and diligence in evaluating the causality of the adverse event under investigation.

GVK Biosciences further drew the attention of the regulator to the fact that the deceased subject had not received the new investigational vaccine and had, in fact, been randomized to receive a marketed reference product that is approved for sale in India by the office of the Drugs Controller General of India, and is widely used in clinical practice in India and abroad. While GVK Biosciences has been unable to find any link between the administered vaccine, or between the

conduct of the study, and the death of the child, it has requested the DCG(I) to let the company know if the inspection team appointed by the regulator has been able to find such a link.