Sub: Update on APIs Chloroquine Phosphate and Hydroxychloroquine Sulphate and its formulations

Dear Sirs

We wish to inform you that due to the shortage implications and/or medical necessity of certain drugs and finished products, the United States Food and Drug Administration (FDA) vide its e-mails dated 20th March, 2020 has made exception to the import alert for the Company’s following Active Pharmaceutical Ingredients (APIs) and finished products (Formulations):

a. Hydroxychloroquine Sulphate and Chloroquine Phosphate APIs produced at the Company’s APIs manufacturing unit situated at Ratlam (Madhya Pradesh); and

b. Hydroxychloroquine Sulphate Tablets produced at the Company’s formulations manufacturing units situated at SEZ Indore, Pithampur (Madhya Pradesh) and Piparia (Silvassa).

US FDA has also informed that their exception will be re-considered if the shortage implications change.

We also wish to bring to your notice several credible articles / reports / research papers claiming prophylactic as well as treatment potentials of Chloroquine Phosphate and Hydroxychloroquine Sulphate formulations in managing/treating Coronavirus Disease (Covid-19), though these drugs are not approved for treatment by any regulatory authority. Due to this, we are noticing an increase in the emergency demand and enquiries for the Chloroquine Phosphate and Hydroxychloroquine Sulphate APIs and its formulations from several countries world over.

Forseeing this increased demand, Ipca being amongst largest manufacturer, vertically integrated with capacities and capabilities for manufacturing of these APIs and its formulations, is gearing to manufacture and supply these products meeting the stringent cGMP, quality and regulatory requirements and thus help mankind in the best possible way in these testing times.

Thanking you

Yours faithfully

For Ipca Laboratories Limited

Harish Kamath
Corporate Counsel & Company Secretary