PANDEMIC AND “INFODEMIC”

Dear Reader,

With the passage of about one year since the outbreak of the COVID-19 pandemic, huge amounts of scientific research data on COVID-19 are being generated daily and we have thus substantial information and understanding of the disease. While treatment with known anti-viral drugs, monoclonal antibodies, steroids and APIs continues, focus is now on the development and manufacturing of effective vaccines to protect the population at large.

Several Indian companies are already conducting pan-India clinical trials of different vaccines. Bharat Biotech, in cooperation with the Indian Council of Medical Research and the National Institute of Virology, has developed a whole-virion inactivated vaccine on an inactivated platform, which will be administered intramuscularly in two doses (0, 28d). Biological E. is clinically evaluating its adjuvant protein subunit (RBD) vaccine on a protein subunit platform, again administered intramuscularly in two doses (0, 28d). Cadila Healthcare has developed a DNA plasmid vaccine on a DNA platform, administered intradermally in three doses (0, 28, 56d). Dr. Reddy's Laboratories, together with the Russian Direct Investment Fund, will be conducting clinical trials of the Sputnik V adenovirus-based vaccine on non-replicating viral vector platform (developed by the Gamaleya National Research Institute). The Serum Institute of India, together with ICMR, is conducting clinical trials of the ChAdOx1-S AstraZeneca-Oxford vaccine on a non-replicating viral vector, also administered intramuscularly in two doses (0, 28d).

Moreover, Indian Immunologicals and Serum Institute are conducting pre-clinical evaluation of their codon de-optimized live attenuated vaccines on live attenuated virus platforms. Bharat Biotech, in cooperation with Thomas Jefferson University, is conducting pre-clinical evaluation of its recombinant deactivated rabies virus containing S1-vaccine on a non-replicating viral vector. It is also planning to manufacture a novel chimp adenovirus, single dose intranasal vaccine after phase I clinical trials are successfully conducted at St. Louis University in the USA. Cadila Healthcare with its measles vector vaccine and Aurobindo with its VSV-S vaccine, both on replicating viral vector platforms, are the other companies already conducting pre-clinical evaluations. Just as the Indian manufacturing pharmaceutical industry is already playing a crucial role in supplying generics, APIs and vaccines globally, these companies are gearing up to serve the global needs for effective remedies against COVID-19.

Worldwide, research on new vaccines is also focussing on a variety of other strategies using DNA plasmids, virus-like particles, CD8 T cell peptide targeting, mRNAs, influenza A virus, horsepox vector, measles vector, outer Drosophila S2 insect cell expression system VLPs, membrane vesicles, structurally modified spherical particles of the tobacco mosaic virus, oral E. coli based protein expression system of S and N proteins, adenovirus, egg-based inactivated whole chimeric Newcastle disease virus protein and more.

Apart from clinical data generated during the treatment of COVID-19 infected patients, a huge amount of clinical data is being generated during the three-phase clinical trials, and the Indian industry has rich experience in conducting clinical research. The race for putting up the first vaccine against COVID-19 is so intense that sometimes serious errors are being committed, such as the “dosing error” recently reported by one of the forefront runners. In the course of time, more information will be available on the interaction of vaccines with other drugs as well as treatment of patients with co-morbidities. The Real-time Reverse Transcription-Polymerase Chain Reaction (RT-PCR) diagnostic method is undergoing refinement to reduce the incidence of false positives. In the areas of formulation of the vaccines, improving shelf-life, pharmacokinetics, administration routes, dosing schedules, ADMET data and packaging, substantial data will have to be generated, evaluated and interpreted to assure stability, efficacy and non-toxicity of the

vaccines. The effect of packaging materials such as vials, stoppers, gauzes and syringes needs to be studied in detail. The effect of “temperature shocks” during transport or storage on the vaccine’s effectiveness also needs to be studied in detail.

Companies are ramping up their production capacities to be able to meet the demand for vaccines. Shortages in raw material supply for vaccine production, glitches in logistics and distribution and other challenges will be needed to be tackled along the way, not only due to the different cold-storage conditions and the infrastructure needed in different regions and countries.

The Indian government, through the concerned ministries, is doing its best to see that reasonably priced vaccines against COVID-19, reach the citizens, beginning with prioritised categories, at the earliest.

While it is the responsibility of the media to keep the general public informed, it is becoming essential to fight, as the WHO describes it, the “infodemic” related to COVID-19. Responsible and unbiased reporting by the various media is the need of the hour. Just as the media does not and cannot assign any nationality to the SARS-CoV-2 virus, nor does this virus differentiate between different human beings when it infects, similarly, the media would do well by refraining from trying to describe the companies, research laboratories and scientists involved in vaccine development and production by various populist connotations.

We at Indian Drugs look forward to receiving scientific articles connected to COVID-19!

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About The Associate Editor

Dr. Nagaraj Narayan Rao obtained Bachelor’s degrees in Science (Chemistry) and in the Technology of Pharmaceuticals and Fine Chemicals from the University of Mumbai. After working with Colgate-Palmolive (India) for two years as a laboratory chemist, he obtained his doctorate in science with *magna cum laude* from the University of Tuebingen, Germany, under the guidance of Prof. Dr. H. J. Roth. He carried out post-doctoral research at the Institute of Biotechnology of the Research Center Juelich, Germany. He was a member of the Editorial Board for the first official German-language version of the European Pharmacopoeia. He was a visiting scientist at Juelich and a visiting faculty at the Institute of Chemical Technology Mumbai from 1993 to 2007 in the field of bioprocess technology. He has authored several original research articles, a patent, review articles and book chapters in the fields of pharmaceuticals, biotechnology, brewery and surface coatings. He was Chief Editor of the “Transactions of the MFAI” for a few years. He contributes a monthly ‘Report from India’ to a leading German technical journal since fourteen years and is a distinguished alumnus of the Research Center Juelich.

Dr. Rao is co-founder of the RRR group of small and medium enterprises, manufacturing organic fine chemicals, formulations for surface coating technologies and fertilizers, process sensors and process units for life sciences, brewery and chemical process industries, as well as representing select overseas companies for cell culture media, bulk drugs and used chemical equipment and plants.

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