PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

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Dr HarshVardhan, MBBS, MS
Union Minister of Health and Family Welfare
Ministry of Health and Family Welfare
Union Minister of Science and Technology
Department of Science & Technology

19 May 2020

Via e-mail: drhrshvardhan@gmail.com; dr.harshvardhan@sansad.nic.in;

Subject: **Human-specific, effective treatments for COVID-19**

Dear Dr Harsh Vardhan Ji,

I am writing on behalf of People for the Ethical Treatment of Animals (PETA) India and our more than 1.5 million members and supporters. We laud your leadership and the efforts of the government to find treatments for COVID-19 that are based on human biology and whose development can avoid the use of inaccurate and inefficient tests on animals. We humbly ask that you further prioritise and invest in modern scientific research and policies for developing humane, human-derived therapeutics, such as convalescent plasma treatment and the use of recombinant human antibodies.

Human-Derived Treatments
In light of promising preliminary data, the US Food and Drug Administration is expediting access to human-derived convalescent plasma, even in advance of human clinical trials. Furthermore, the Indian Council of Medical Research has invited applications from government-run hospitals and centres to participate in an open randomised trial to assess the safety and efficacy of using convalescent plasma.

The basic principle behind the convalescent plasma approach is that serum donated by patients who have fully recovered from COVID-19[1] can be used to treat infected patients. A similar approach[2] has been used previously to develop other antibody-based therapies.[3,4] It is evident that convalescent plasma is a valuable treatment option that can be used in the immediate future,[5] while other human-relevant treatments for COVID-19 can be developed in the longer term.

The therapeutic antibodies that make convalescent plasma such an effective treatment can be produced on an industrial scale using existing methods, which would help ensure that cases of COVID-19 could be treated without the continual need to obtain convalescent plasma from human volunteers. One of these methods – phage display – creates recombinant human antibodies using cultured cells. Several recombinant antibodies[6] are already on the market, and many more are being developed.[7]

Effective Toxicity Tests on Animals

The current pandemic presents an opportunity to set new and improved standards for testing the safety and efficacy of new therapeutics. Recent actions by regulatory agencies and governing bodies in India and around the world have shown that regulations requiring extensive animal testing before human clinical trials are unnecessary barriers to introducing lifesaving drugs. More than 95% of drugs that pass the currently required animal tests ultimately fail in humans, which exemplifies the need for more human-relevant approaches to ensuring that new drugs are safe and effective.[8]

As mentioned above, we appreciate the government's efforts to control COVID-19 by developing human-derived treatments and introducing improved standards for demonstrating the safety and relevance to humans of these drugs without necessarily relying on ineffective animal tests. We ask that you prioritise investment in modern, non-animal scientific research and update policies and regulations to facilitate the development of humane, human-derived therapeutics for treating COVID-19 and other diseases which would allow for prompt action in the future. To help achieve this goal, we have attached for your consideration a detailed plan of action with strategic priorities for modernising research and testing in India. The report can be accessed from here

I respectfully request that your good office appoint the relevant officers from the Ministry of Health and Family Welfare and the Ministry of Science & Technology to schedule a teleconference with me to discuss this important issue. I can be contacted on +91 8800897382 or at DiptiK@petaindia.org. I look forward to hearing from you.

Kind regards,

Dipti M Kapoor, PhD
Science Policy Adviser

Annexures:

1. Research Modernisation Deal with strategic priorities for modernising research and testing in India
2. Notice from the Central Drugs Standard Control Organisation encouraging the development of research and a vaccine to prevent COVID-19

References

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[4]Cheng, Y., Wong, R., Soo, Y.O., Wong, W.S., Lee, C.K., Ng, M.H., . . . Cheng, G. (2005). Use of convalescent plasma therapy in SARS patients in Hong Kong. *Eur. J. Clin. Microbiol. Infect. Dis.*, 24(1), 44–46.
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[6]The Serum Institute of India has manufactured a recombinant antibody drug that has been approved to treat rabies virus infections. Available at https://www.seruminstitute.com/product_ind_rabishield.php.
[7]Wenzel, E.V., Bosnak, M., Tierney, R., Schubert, M., Brown, J., Dübel, S., . . . Hust, M. (2020). Human antibodies neutralizing diphtheria toxin *in vitro* and *in vivo*. *Sci. Rep.*, 10, 1–21. This project was initiated in response to requests from global health agencies seeking a replacement for the conventional horse blood–derived diphtheria treatment, which can cause serious allergic reaction, and was funded by the PETA International Science Consortium Ltd.
[8]National Center for Advancing Translational Sciences, "About NCATS" <https://ncats.nih.gov/about>.