PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

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VG Somani, PhD
Drugs Controller General of India
Central Drugs Standard Control Organization
Union Minister of Health and Family Welfare
Ministry of Health and Family Welfare

18 June 2020

Via e-mail: dci@nic.in

Subject: **Effective Treatments for COVID-19**

Dear Dr Somani,

On behalf of People for the Ethical Treatment of Animals (PETA) India and our more than 1.5 million members and supporters, I am writing to express our strong support of the Central Drugs Standard Control Organisation (CDSCO) policies that aim to expedite the development of safe, effective COVID-19 therapies using modern, human-relevant testing strategies. In addition to fostering the rapid development of treatments, vaccines, and diagnostic tools to address this pandemic, these policies will improve the processes used by industry and regulatory agencies to develop other new medical treatments. 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.

Prioritise Human-Derived Treatments
In light of promising preliminary data, agencies around the world, including the US Food and Drug Administration and CDSCO, are expediting access to humanderived convalescent plasma, even in advance of human clinical trials. One treatment uses antibodies from serum donated by patients who have recovered from an infection or disease. A similar approach[1] involving convalescent plasma was previously used to develop other antibody-based therapies.[2,3]

The therapeutic antibodies that make convalescent plasma such an effective treatment can be produced on an industrial scale by employing existing methods without using animals, 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.

For scientific and ethical reasons, a key European government organisation has recommended an end to using animals to produce antibodies.[4] Not only are nonanimal antibodies more scientifically robust, they can also be made more quickly than animal-derived antibodies. To give one example, as early as 25

March, the company YUMAB announced that it had generated and characterised the first human antibodies against the new coronavirus strain,[5] and it has since confirmed therapeutic effects by using the patient-derived coronavirus strain SARS-CoV-2.[6] These human antibodies are currently being developed into a treatment that can be assessed in human clinical trials.

Ineffective Toxicity Tests on Animals

The current pandemic presents an opportunity to establish new and improved standards for testing the safety and efficacy of new therapeutics. A recent announcement by CDSCO lists the regulatory pathway for research and development for drugs and vaccines, and regulatory agencies 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 ensure that new drugs are safe and effective.[7]

We appreciate CDSCO's efforts to control COVID-19 by supporting humanderived treatments and introducing improved standards for demonstrating the safety and relevance to humans of these drugs without relying on animal tests. We ask that you further prioritise investment and update policies and regulations to facilitate the development of humane, human-derived therapeutics for treating COVID-19 and other diseases. To help achieve this goal, we have attached for your consideration a detailed strategic priorities for modernising research and testing in India.

I respectfully request that your good office schedule a meeting with me at your earliest convenience to discuss the integration of these recent policy changes in response to COVID-19 into CDSCO's broader approach to the development and testing of new therapies. 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:

- Research Modernisation Deal with strategic priorities for modernising research and testing in India
- Notice from the Central Drugs Standard Control Organisation regarding regulatory pathways for R&D for drugs and vaccines to prevent COVID-19

[1]Huo, X., Sun, X., Lan, K., & Wu, J. (2016). Treatment-donation-stockpile dynamics in ebola convalescent blood transfusion therapy. *J. Theor. Biol.*, *392*, 53-61.
[2]Hung, I.F., To, K.K., Lee, C.K., Lee, K.L., Chan, K., Yan, W.W., . . . Yuen, K.Y. (2011). Convalescent plasma treatment reduced mortality in patients with severe pandemic influenza A (H1N1) 2009 virus infection. *Clin. Infect. Dis.*, *52*(4), 447-456.

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[3]Cheng, Y., Wong, R., Soo, Y.O.Y., Wong, W.S., Lee, C.K., Ng, M.H.L., . . . Cheng, G. (2005). Use of convalescent plasma therapy in SARS patients in Hong Kong. *Eur. J. Clin. Microbiol. Infect. Dis.*, *24*(1), 44-46.
[4]*EURL ECVAM recommendation on non-animal-derived antibodies*. (2020, May 14). EU Science Hub. https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/eurlecvam-recommendation-non-animal-derived-antibodies
[5]*COVID-19: First step towards antibody therapy*. (2020, March 25). YUMAB.com. https://www.yumab.com/partnership-with-boehringer-ingelheim/
[6]*YUMAB identifies promising candidate for Covid-19 antibody therapy*. (2020, May 7). YUMAB.com. https://www.yumab.com/wp-content/uploads/2020/05/2020.05.08_PR_SARS-CoV-2_ENG_final.pdf
[7]National Center for Advancing Translational Sciences. (n.d.). *About NCATS*. NIH.gov. https://ncats.nih.gov/about