PEOPLE FOR
THE ETHICAL
TREATMENT
OF ANIMALS

PO Box 70315
London N1P 2RG
United Kingdom
+44 (0) 20 7837 6327
+44 (0) 20 7923 6242 (fax)

Info@peta.org.uk

Guido Rasi
Executive Director
European Medicines Agency

13 May 2020

Via e-mail: Guido.Rasi@ema.europa.eu

Dear Professor Rasi,

On behalf of People for the Ethical Treatment of Animals (PETA) Foundation and our more than 1.3 million members and supporters, I am writing to express our strong support of the European Medicines Agency's (EMA) 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 present an unparalleled opportunity to improve the processes used by industry and regulatory agencies to develop new medical treatments.

Prioritise Human-Relevant Methods

We welcome EMA's commitment to applying the 3Rs in the regulatory testing of medicinal products and applaud its work to date in this area, and we agree with the section of the "EMA Regulatory Science to 2025" document[1] that describes the agency's strategy for encouraging the development and uptake of New Approach Methodologies. Now, perhaps more than ever before, people need strategies that will bring medical products to market faster and with greater assurances of safety. Replacing reliance on animal testing with new tools and technology that better predict human responses is one such strategy. We therefore ask that you consider prioritising this commitment in light of the COVID-19 pandemic.

As stated in the summary report of the International Coalition of Medicines Regulatory Authorities' first Global Regulatory Workshop on COVID-19 Vaccine Development,[2] "[t]he rapid spread of SARS-CoV-2 requires accelerated development timelines for SARS-CoV-2 vaccine candidates to enter expeditiously into Phase 1 clinical trials". The workshop identified that some preclinical data usually required prior to human trials could be bypassed without jeopardising human health where an established platform technology is used. Indeed, the US Food and Drug Administration took this approach in its review of the investigational new drug application for the COVID-19 vaccine candidate jointly developed by Moderna and the US National Institutes of Health,[3] which allowed the vaccine to enter clinical trials without first undergoing the routine suite of animal tests. We suspect this may have also been the case with other vaccines.[4,5] We support these decisions and request that this approach be extended beyond COVID-19 to cover the development of all drugs.

Avoid Falling Back on Old Methods

Regulatory agencies around the world are responding to the urgency of this crisis by granting new drug sponsors flexibility in proposing innovative strategies that replace animal use. As EMA moves forward, we urge you to leverage the lessons learned during the coronavirus pandemic to expedite acceptance of modern toxicological methods that assure new therapies are safe, effective, and accessible. As illustrated by the rapid movement towards clinical trials of vaccines and therapies such as human convalescent plasma,[6] EMA must seize this opportunity to take decisive action to support its goals of modernising and accelerating drug development by pivoting towards the use of available human-relevant, animal-free test methods.

In the existing process, more than 95% of new drugs that pass currently required animal tests ultimately fail in humans.[7] The coronavirus pandemic has emphasised the need to replace the lengthy, animal-intensive drug development process with an approach that efficiently and effectively identifies life-saving human treatments. We applaud EMA's role in pushing humane science forward during this pandemic and call on the agency to continue prioritising a transition to human-relevant methods well beyond COVID-19.

I would appreciate it if, at your earliest convenience, you would inform me of EMA's plans to integrate these recent policy changes in response to COVID-19 into the agency's broader approach to the development and testing of new therapies. If you are available for a teleconference to discuss this important matter, please let me know. I can be reached at SamanthaSaunders@peta.org.uk.

Sincerely,

Samantha Saunders, PhD
Research Associate

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[1]European Medicines Agency. EMA regulatory science to 2025: Strategic reflection. 2020. https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/ema-regulatory-science-2025-strategic-reflection_en.pdf. Accessed 13 May 2020.

[2]International Coalition of Medicines Regulatory Authorities. Global regulatory workshop on COVID-19 vaccine development: Summary report. 2020. http://www.icmra.info/drupal/sites/default/files/2020-03/First%20regulatory%20COVID-19%20workshop%20-%20meeting%20report_March%202020.pdf. Accessed 13 May 2020.

[3]Moderna. Moderna's work on a potential vaccine against COVID-19. https://www.modernatx.com/modernas-work-potential-vaccine-against-covid-19. Accessed 13 May 2020.

[4]Lane R. Sarah Gilbert: Carving a path towards a COVID-19 vaccine. *Lancet*. 2020:395(10232):1247. https://doi.org/10.1016/S0140-6736(20)30796-0.

[5]Sample I. Trials to begin on Covid-19 vaccine in UK next month. *The Guardian*. 19 March 2020. https://www.theguardian.com/society/2020/mar/19/uk-drive-develop-coronavirus-vaccine-science. Accessed 13 May 2020.

[6]EudraCT Number 2020-001310-38. EU Clinical Trials Register. https://www.clinicaltrialsregister.eu/ctr-search/trial/2020-001310-38/DE. Accessed 13 May 2020.

[7]Hartung T. Look back in anger – what clinical studies tell us about preclinical work. *ALTEX*. 2013;30(3):275-291. https://doi.org/10.14573/altex.2013.3.275.