PEOPLE FOR
THE ETHICAL
TREATMENT
OF ANIMALS

Stichting PETA Nederland
Postbus 2570
1000 CN Amsterdam
0900 - 235 7382
(0900 - BEL PETA)

Info@peta.nl
PETA.nl

Ton de Boer
Chair
College ter Beoordeling van Geneesmiddelen

13 May 2020

Via e-mail: info@cbg-meb.nl

Dear Professor de Boer,

On behalf of People for the Ethical Treatment of Animals (PETA) Netherlands and PETA UK, I am writing to express our strong support of policies such as those of the US Food and Drug Administration that aim to expedite the development of safe, effective SARS-CoV-2 vaccines and 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 the College ter Beoordeling van Geneesmiddelen's (CBG) commitment to working towards reducing the use of animals in the regulatory testing of medicinal products – as shown, for example, by your recent column "Dierproeven: van onvermijdelijk naar overbodig?"[1] – and making the principle of the 3Rs the central theme of CBG's yearly Science Day in 2019. We applaud the work of CBG's scientific department in this area to date, such as Dr Theunissen's important research,[2,3] which has contributed to the update of an international guideline for pharmaceutical products on toxicity during reproduction, preventing an estimated 300,000 to 400,000 animals every year from being used in tests. In addition, the ground-breaking research by Dr Van der Laan[4] is likely to have similar success in the field of regulatory testing for carcinogenicity. We strongly support the aim of CBG to "continue to work on reducing animal testing", as stated in CBG's Strategic Business Plan 2020–2024.[5] 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 SARS-CoV-2 pandemic.

As stated in the summary report from the first Global Regulatory Workshop on COVID-19 Vaccine Development of the International Coalition of Medicines Regulatory Authorities,[6] of which CBG is a member, "[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

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Administration took this approach in its review of the investigational new drug application for the SARS-CoV-2 vaccine candidate jointly developed by Moderna and the US National Institutes of Health,[7] 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.[8,9] We support these decisions and request that this approach be extended beyond SARS-CoV-2 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 the CBG 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,[10] the CBG 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.[11] 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 the CBG'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 SARS-CoV-2.

I would appreciate it if, at your earliest convenience, you would inform me of the CBG's plans to integrate these recent policy changes in response to SARS-CoV-2 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 JannekeH@peta.org.uk.

Sincerely,

Janneke Hogervorst, PhD
Science Adviser – the Netherlands
PETA UK
On behalf of PETA Netherlands

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[1]De Boer, T. Column Over medicijnen: Dierproeven: van onvermijdelijk naar overbodig? *Leidsch Dagblad*. 5 February 2020. https://www.leidschdagblad.nl/cnt/dmf20200204_41936189/over-medicijnen-dierproeven-van-onvermijdelijk-naar-overbodig. Accessed 13 May 2020.

[2]Theunissen PT, Beken S, Beyer BK, *et al*. Comparison of rat and rabbit embryo-fetal developmental toxicity data for 379 pharmaceuticals: on the nature and severity of developmental effects. *Crit Rev Toxicol*. 2016;46(10):900-910.

[3]Theunissen PT, Beken S, Beyer B, *et al*. Comparing rat and rabbit embryo-fetal developmental toxicity data for 379 pharmaceuticals: on systemic dose and developmental effects. *Crit Rev Toxicol.* 2017;47(5):402-414.

[4]Woutersen RA, Soffers AE, Kroese ED, *et al*. Prediction of carcinogenic potential of chemicals using repeated-dose (13-week) toxicity data. *Regul Toxicol Pharmacol.* 2016;81:242-249.

[5]College ter Beoordeling van Geneesmiddelen. Strategisch business plan 2020–2024. 21 April 2020. https://www.cbg-meb.nl/onderdelen/over-cbg/documenten/publicaties/2020/01/01/strategisch-business-plan-2020-2024. Accessed 13 May 2020.

[6]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.

[7]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.
[8]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.
[9]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.
[10]EudraCT Number 2020-001310-38. EU Clinical Trials Register. https://www.clinicaltrialsregister.eu/ctr-search/trial/2020-001310-38/DE. Accessed 13 May 2020.
[11]Hartung T. Look back in anger – what clinical studies tell us about preclinical work. A*LTEX*. 2013;30(3):275-291. https://doi.org/10.14573/altex.2013.3.275.