



Medicines & Healthcare products
Regulatory Agency



MHRA

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Ms W van Bentum-Puijk
UNIVERSITY MEDICAL CENTRE UTRECHT
CELL THERAPY FACILITY, HEIDELBERGLAAN 100, UTRECHT, NL-3584 CX, NETHERLANDS

17/03/2021

Dear Ms W van Bentum-Puijk,

THE MEDICINES FOR HUMAN USE (CLINICAL TRIALS) REGULATIONS 2004 S.I. 2004/1031

Our Reference:	CTA 30913/0006/001-0017
Eudract Number:	2015-002340-14
Product:	ceftriaxone, levofloxacin, piperacilin-tazobactam, hydrocortisone, amoxicillin-clavulanate, azithromycin, clarithromycin, moxifloxacin, ceftaroline, hydroxychloroquine, Tocilizumab, Sarilumab, Heparin, Sarilumab unlicensed, Kaletra 80mg/20mg Oral Solution, interferon beta-1a, anakinra, Lopinavir/Ritonavir Mylan, Ascorbic Acid, simvastatin, Ramipril, Lisinopril, Perindopril, Enalapril, Captopril, losartan, Valsartan, Candesartan, Irbesartan
Protocol number:	n/a
Substantial Amendment Code Number:	AM025

NOTICE OF ACCEPTANCE OF AMENDMENT

I am writing to inform you that the Licensing Authority accepts the proposed amendment to your clinical trial authorisation (CTA), received on 11/03/2021.

MEDICAL - Remarks: Remarks (for information);

The ACE2 Renin-Angiotensin System (RAS) Modulation Domain includes the novel drug DMX-200. The MHRA have not approved the use of this IMP as part of this substantial amendment and instead are awaiting a future substantial amendment to include the IMP, as per the cover letter provided with this amendment (please note also that the Expert Advisory Group will review the request to add this IMP when the request is formally made by the Sponsor). The Sponsor is reminded that patient facing documents, such as the PIL's should not be submitted to the MHRA, given such documents are reviewed by the REC and not the MHRA.
For further information contact lisa.campbell@mhra.gov.uk

This amendment may therefore be made.



If applicable, you should ensure your trial details have been updated on the database where you have registered your trial.

You are reminded that where it is appropriate, the Ethics Committee should also be notified of amendments.

Yours sincerely,

Clinical Trials Unit
MHRA