



Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

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

30/07/2026

Dear Ms W van Bentum-Puijk,

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

Our Reference
EUDRACT Number
Product

CTA 30913/0006/001-0040
2015-002340-14
ceftriaxone, 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, Repagermanium, cysteamine bitartrate, Clopidogrel, Prasugrel, Aspirin, ticagrelor, Pascorbin, Casirivimab / imdevimab (Ronapreve), Pascorbin / Ascorbic Acid, Dexamethasone, Xofluza, Tamiflu, Baricitinib, 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, Repagermanium, cysteamine bitartrate, Clopidogrel, Prasugrel, Aspirin, ticagrelor, Pascorbin, Casirivimab / imdevimab (Ronapreve), Pascorbin / Ascorbic Acid, Dexamethasone, Xofluza, Tamiflu, Baricitinib

Protocol Number

n/a

Substantial Modification Code Number

SA044

NOTICE OF ACCEPTANCE OF SUBSTANTIAL MODIFICATION

This letter refers to your modification request received on 23/06/2026.

The licensing authority accepts the proposed substantial modification to your clinical trial authorisation (CTA), including the labelling, subject to any conditions.

SCIENTIFIC - Remarks: A response is required and to be submitted via email below:

A statement made in the cover letter “planned protocol changes to the REMAP-CAP trial. We then proceeded to submit Am44 to the REC and believed also to have submitted to the MHRA at the same time” – Clarification is required if MHRA were to receive any updated protocol document as there were no such documentation been submitted in this application.

If you have a query on these comments, please contact Mrs Hedwig Ganguly on hedwig.ganguly@mhra.gov.uk and clintrialhelpline@mhra.gov.uk

You are reminded that, where appropriate, a favourable opinion from the ethics committee is also required before this modification can be made (please refer to the Modification Tool outcome).

Please ensure that the public registry where you have registered your trial has been updated to reflect any relevant changes.

Yours sincerely,

**Clinical Investigations & Trials
MHRA**