

MHRA

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

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

02/06/2020

Dear Ms W van Bentum-Puijk

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

Our Reference:	CTA 30913/0006/001-0009
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
Protocol Number:	n/a
Substantial Amendment Code Number:	Code Number: AM018 Version: 1 Date: 2020/06/01

ACKNOWLEDGEMENT OF AMENDMENT

Thank you for your notice of amendment, received on 01/06/2020. The information you provided to support your request is complete and therefore your request is valid.

Your request will be assessed and you will be notified of the Licensing Authority's decision within 35 days.

Please quote the EudraCT number, CTA number and your amendment code in any further communications relating to this submission.

Yours sincerely,

Submissions
MHRA