



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

03/06/2020

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

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 01/06/2020.

This amendment may therefore be made.

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

Yours sincerely,

**Clinical Trials Unit
MHRA**