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

28/12/2023

Dear Ms W van Bentum-Puijk

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

Our Reference:	CTA 30913/0006/001-0035
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, Repagermanium, cysteamine bitartrate, Clopidogrel, Prasugrel, Aspirin, ticagrelor, Pascorbin, Casirivimab / imdevimab ( Ronapreve), Pascorbin / Ascorbic Acid, Dexamethasone, Xofluza, Tamiflu, Baricitinib
Protocol Number:	n/a
Substantial Amendment Code Number:	AM040

**ACKNOWLEDGEMENT OF AMENDMENT**

Thank you for your notice of amendment, received on 22/12/2023. 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**