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

06/12/2019

Dear Ms W van Bentum-Puijk,

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

Our Reference:	CTA 30913/0006/001-0002
Eudract Number:	2015-002340-14
Product:	ceftriaxone, levofloxacin, piperacilin-tazobactam, hydrocortisone, amoxicillin-clavulanate, azithromycin, clarithromycin, moxifloxacin, ceftaroline
Protocol number:	n/a
Substantial Amendment Code Number:	Code Number: AM05 Version: 1.0 Date: 2019/11/12

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 29/11/2019.

MEDICAL - Remarks: Remarks:
The following comments are for future consideration / information only and do not affect the approval status of your study. No response is required.
1. The Sponsor should note that as per routine assessment process the Substantial Amendment has not been assessed from a statistical point of view by the UK Regulatory authority. A statistical review will be performed by the Ethics committee. The substantial amendment is however approved in its entirety (as presented) by the MHRA.
For addition information email lisa.campbell@mhra.gov.uk.

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

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