MHRA
151 Buckingham Palace Road
London SW1W 9SZ
United Kingdom

mhra.gov.uk

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

01/06/2018

Dear Ms W van Bentum-Puijk

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

Our Reference:	30913/0006/001-0001
Eudract Number:	2015-002340-14
Product:	ceftriaxone
Protocol number:	n/a

NOTICE OF ACCEPTANCE OF AMENDED REQUEST

I am writing to inform you that the Licensing Authority accepts your amended request for a clinical trial authorisation (CTA), received on 29/05/2018.

The authorisation is effective from the date of this letter although your trial may be suspended or terminated at any time by the Licensing Authority in accordance with regulation 31. You must notify the Licensing Authority within 90 days of the trial ending.

Finally, you are reminded that a favourable opinion from the Ethics Committee is also required before this trial can proceed; changes made as part of your amended request may need to be notified to the Ethics Committee.

Yours sincerely,

Clinical Trials Unit
MHRA