Medicines & Healthcare products Regulatory Agency

MHRA

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Dr P Bath
UNIVERSITY OF NOTTINGHAM
AUI MENTAL HEALTH AND CLINICAL NEUROSCIENCES,
QUEEN'S MEDICAL CENTRE, DERBY ROAD
NOTTINGHAM
NG7 2UH
UNITED KINGDOM

03/11/2021

Dear Dr P Bath,

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

Our Reference:	CTA 03057/0074/001-0001
Eudract Number:	2021-001050-62
Product:	Cyklokapron
Protocol number:	21022

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 17/09/2021.

PHARMACEUTICAL - Remarks: Authorisation of your clinical trial is subject to the following condition:

* The application form should be updated to show that the IMP is defined by active substance only, rather than by a specific product, and submitted as part of the next substantial amendment.

If this condition is met, the trial is authorised and you do not need to respond to this letter. If your trial does not meet this condition, your trial does not have authorisation and therefore you can not proceed with the trial. You must inform the MHRA immediately if the trial does not meet the above condition. All changes to the terms and conditions of this trial must be made as a request for a substantial amendment to this clinical trial authorisation. For further information on the above, please contact Dr Simon Lewis on 020 3080 6621 or simon.lewis@mhra.gov.uk.

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.

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. If not already provided, please follow the guidance on our website on informing us of the registration status of your trial (where applicable).

You are reminded that from 1 January 2022 you will need to comply with the requirements specified in the following guidance, where applicable:

- ***Import of IMPs from listed countries to GB:***

https://www.gov.uk/government/publications/importing-investigational-medicinal-products-into-great-britain-from-approved-countries

- ***Supply of IMPs to Northern Ireland:***

https://www.gov.uk/guidance/supplying-investigational-medicinal-products-to-northern-ireland

- ***Substantial amendments to clinical trials:***

https://www.gov.uk/guidance/guidance-on-substantial-amendments-to-a-clinical-trial

Any required substantial amendment to your Clinical Trial Authorisation should be submitted and approved as soon as possible and before 1 January 2022.

Yours sincerely,

Clinical Trials Unit
MHRA