

Appendix 1 – MHRA permission for CTU to perform IMP Labelling

Appendix 1.1 – MHRA permission for CTU to perform Azithromycin Labelling

From: "McNaughton, Graham" <Graham.McNaughton@mhra.gov.uk>

Subject: RE:Azithromycin distribution from Oxford Clinical Trials Unit to participants in PRINCIPLE TRIAL?

Date: 5 May 2020 at 15:08:36 BST

To: Christopher Butler <christopher.butler@phc.ox.ac.uk>

Cc: "Wydenbach, Kirsty" <Kirsty.Wydenbach@mhra.gov.uk>, Kevin Ahmed <Kevin.Ahmed@hra.nhs.uk>, Emma Ogburn <emma.ogburn@phc.ox.ac.uk>, "Richard Hobbs" <richard.hobbs@phc.ox.ac.uk>

Dear Chris,

Thank you for providing the additional clarification regarding your proposal for a solution to the temporary supply chain issue relating to the azithromycin. Your suggestion that the labelling is performed by a registered GP and checked/supervised by a pharmacist sound sensible precautions. It is important that the correct labelling is applied and that this does not obscure any of the information on the original packaging; to that end there should be a clear procedure in place to ensure that this is the case.

The MHRA understands that this solution only relates to the current supply of azithromycin, that has arrived at Public Health England, and is already boxed for each patient course. Further, it is our understanding that this solution will only be applied until such a time as azithromycin labelled by Fisher Clinical Services become available.

Please do contact me on the number below if you require any clarification or wish to discuss this further.

Kind regards,

Graham

Graham McNaughton PhD

Leading Senior Pharmaceutical Assessor
Clinical Trials Unit

Licensing Division

Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU
Direct line: 020 3080 6148.
graham.mcnaughton@mhra.gov.uk

Appendix 1.2 MHRA permission for CTU to perform Doxycycline Labelling

From: Christopher Butler <christopher.butler@phc.ox.ac.uk>
Sent: 24 June 2020 17:10
To: McNaughton, Graham <Graham.McNaughton@mhra.gov.uk>
Cc: Wydenbach, Kirsty <Kirsty.Wydenbach@mhra.gov.uk>; Kevin Ahmed <Kevin.Ahmed@hra.nhs.uk>; Emma Ogburn <emma.ogburn@phc.ox.ac.uk>; Hannah Swayze <hannah.swayze@phc.ox.ac.uk>
Subject: Re: Doxycycline: distribution from Oxford Clinical Trials Unit to participants in PRINCIPLE TRIAL?

Dear Graham,

Thank you very much for your email and confirmation. This will allow us to efficiently begin recruitment to the new arm as soon as the approvals are in place. Please see below answers to your questions.

1. We are currently seeking Sponsor and UPH approvals to add the doxycycline arm to the trial and as soon as we have approvals, we will contact Fisher regarding the additional re-labelling. They have previously provided us with an expected time-frame of 6 week from receipt of the drugs to dispatch, but of course this is dependent on their capacity at this time.
2. The packs of labelled Azithromycin were delivered to the Oxford University Primary Care Clinical Trials Unit on 18th June 2020.
3. Further treatment arms to the trial are being developed in line with the current literature and discussions amongst the investigators. These treatments are yet to be agreed and confirmed and as soon as they are, we will discuss re-labelling time-lines with Fisher.

With thanks and best wishes

Chris

Christopher C. Butler

BA MBChB DCH CCH MD FRCGP FFP(Hon) FMedSci

On 23 Jun 2020, at 11:21, McNaughton, Graham <Graham.McNaughton@mhra.gov.uk> wrote:

Dear Chris,

Following discussion with colleagues, it has been agreed that we would have no objection to the temporary use of PCCTU for labelling of the initial doxycycline supplies until such a time as doxycycline labelled by Fisher Clinical Services becomes available.

However, my colleagues did have several points, which I would be grateful if you could comment on at your earliest convenience:

1. Can you confirm that Fisher have been formally contracted to undertake labelling of doxycycline? If so, what is the expected timeline for them to commence their supply of labelled product?
2. Can you confirm the date from which the supply of azithromycin, labelled by Fisher, commenced?
3. Are there plans to add further arms to this trial? If so, is it possible to reduce the lag time for commencement of Fisher-labelled supplies?

Kind regards,

Graham

Graham McNaughton PhD

Leading Senior Pharmaceutical Assessor
Clinical Trials Unit

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