

Will leave this with you now in planning.

From: [REDACTED]
Sent: 21 October 2025 18:34
To: [REDACTED]
Cc: [REDACTED]
Subject: RE: Exchange Supplies

Hi [REDACTED],

Thanks for this. I [REDACTED]

[REDACTED]

I agree that the risk assessment RE the product and operations remains mitigated by the steps we have taken but would like to get there 4-8 weeks after we receive the variation, ideally short notice.

Best,



[REDACTED]

Subject: Exchange Supplies

Hi All,

Please see below and my response so it can be picked up in my absence but also, so you have a record in case it forms part of any future FOI request when I'm [REDACTED]

My suggestion is if the variation is as expected after a full review, we AWI the RP change and new site onto the licence and due to the potential noncompliance historically [REDACTED] new site is up and running. I believe the RP is an experienced contract RP after a person search, however this will form part of the full review and information provided once the variation is submitted.

Due to the nature of the products and feedback from assessors, the risk to the public is negatable so I still don't feel we need to do an urgent unannounced inspection. The LH has already stated this activity has stopped, my concern now is with the lack of RP hence my email response below.

Happy as always to hear other suggestions if any of you think we should be taking a different course of action.

Kind Regards

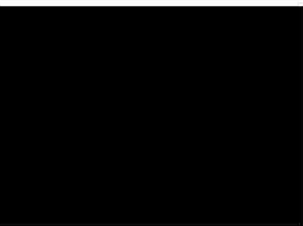
[REDACTED]
[REDACTED]
Sent: 21 October 2025 15:54

[REDACTED]
Subject: RE: Inspection Notification

Dear [REDACTED]

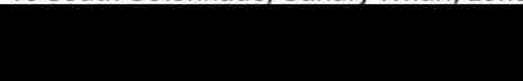
Thank you for the update, please can the variation to add [REDACTED] RP be submitted as soon as possible to ensure compliance to the Human Medicine Regulations 45(1) and 45(4). You may need to split the variation into two parts as I understand you are not currently in compliance due to [REDACTED]. The variation to add the new site can then be submitted once the first variation is approved and once the site is inspection ready if it isn't currently at that stage.

Kind Regards



Standards and Compliance

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade, Canary Wharf, London, E14 4PU



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Sent: 21 October 2025 11:24



Subject: Re: Inspection Notification

Hi 

Apologies for the delay in getting back to you. We will be able to provide a more comprehensive update next week.

The current status is that we had  on site for a 2-day audit of our processes and activities on Thursday 2nd, and Friday 3rd of October. He has made some recommendations for improvements to our Quality Management System and record keeping that we are working our way through.

As  we agreed that we need to engage the services of a consultant Responsible Person to oversee our wholesale

dealer activities. He has referred us to [REDACTED] (cc'd) who we are going to contract as a consultant RP. [REDACTED] contract will begin when she has completed her initial site visit and process review which is happening next week on the 28th.

Once engaged, [REDACTED] will begin the process of preparing the application for the addition of the second site to our Wholesale Dealer Licence.

Meanwhile, you can be assured that all medicines storage and activities related to our Wholesale Dealer Licence are being conducted on our licenced premises.

kind regards,

[REDACTED]

[REDACTED]

Date: Friday, 17 October 2025 at 15:27

[REDACTED]

Subject: RE: Inspection Notification

Dear [REDACTED]

Please can I have an update, and can you confirm when the variation will be submitted in regard to the RP as per your below email.

Kind Regards

[REDACTED]

Standards and Compliance

Medicines and Healthcare products Regulatory Agency (MHRA)
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[REDACTED]

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