

Leon Peto

From: Danny Palmer <Danny.Palmer@uhbw.nhs.uk>
Sent: 01 December 2022 15:36
To: Richard Haynes; Recovery Trial; Marjia.Monsur@dhsc.gov.uk
Cc: Andrea Craddock-Bamford; Leon Peto
Subject: RE: Short dated molnupiravir & paxlovid

Just off of a DHSC call ... The Monupiravir DHCP letter should be in circulation on Monday

Danny

From: Richard Haynes <richard.haynes@ndph.ox.ac.uk>
Sent: 01 December 2022 15:15
To: Danny Palmer <Danny.Palmer@uhbw.nhs.uk>; Recovery Trial <recoverytrial@ndph.ox.ac.uk>; Marjia.Monsur@dhsc.gov.uk
Cc: Andrea Craddock-Bamford <andrea.craddock-bamford@ndph.ox.ac.uk>; Leon Peto <leon.peto@ndph.ox.ac.uk>
Subject: RE: Short dated molnupiravir & paxlovid

Dear Danny

Thank you very much for this. It's very useful information as we'd started to get some queries from sites.

Bw

Richard

From: Danny Palmer <[Danny.Palmer@uhbw.nhs.uk](mailto: Danny.Palmer@uhbw.nhs.uk)>
Sent: 01 December 2022 14:26
To: Recovery Trial <[recoverytrial@ndph.ox.ac.uk](mailto: recoverytrial@ndph.ox.ac.uk)>; [Marjia.Monsur@dhsc.gov.uk](mailto: Marjia.Monsur@dhsc.gov.uk); Richard Haynes <[richard.haynes@ndph.ox.ac.uk](mailto: richard.haynes@ndph.ox.ac.uk)>
Cc: Andrea Craddock-Bamford <[andrea.craddock-bamford@ndph.ox.ac.uk](mailto: andrea.craddock-bamford@ndph.ox.ac.uk)>
Subject: Short dated molnupiravir & paxlovid

Afternoon all,

We've been in discussion with DHSC over the last couple of months regarding the shelf-life extension of Molunpiravir and Paxlovid. Some of our colleagues will be sitting on stock that is expiring at the end of December, and asking how they should manage supply.

DHSC have provided the following statement, and we're expecting advice on the BSV to be circulated any time soon ... Paxlovid will follow shortly afterwards. I think at present this advice should sit with all acute sites' procurement leads, so nothing really required of you or your colleagues unless you are fielding questions. Important thing to note really is that there is short-dated stock still in the distribution network, so Trusts shouldn't be ordering replacement stock as they'll just be adding to the short-dated stock held locally. They just need to sit tight and wait for the DHCP letters

I hope that makes sense

Communication for local NHS trusts – relabelling and batch specific variations of antivirals
We are aware that some NHS Trusts have raised queries regarding how to manage antiviral stock where shelf-life extension has been approved by the MHRA, but the product packaging shows a short expiry date. We wanted to send an update from the Antivirals and Therapeutics Taskforce in

DHSC regarding measures that we are taking to manage DHSC-held stock and which may also be useful for local NHS service providers.

We have been working with MSD and Pfizer to extend the shelf-life of their products. Both molnupiravir and nirmatrelvir + ritonavir have received approval of shelf-life extension from the MHRA. In October 2022, molnupiravir received an extension to 30-month shelf-life and nirmatrelvir + ritonavir to 24-month shelf-life.

Following this approval of shelf-life extension, we have been working with both manufacturers regarding applications for batch specific variations (BSV) to extend the shelf-life of the affected batches of product beyond the labelled expiry date on the pack. This includes a Dear Healthcare Professional Communication (DHPC) which can be attached to the antiviral packs explaining the extended shelf-life. Additionally, patient guidance has also been approved, which will be published on gov.uk to outline which packs of the product have an extended shelf-life and reassure patients that their medicine will continue to work safely over the extended-use period.

The BSV for molnupiravir has been approved by the MHRA and the DHPC letter will shortly be available for dissemination. The BSV application for nirmatrelvir + ritonavir is in the process of being finalised and should be submitted to the MHRA shortly.

It is for local NHS service providers to determine how they manage the stock they hold. The DHPC letter and accompanying patient guidance will be available so that, if appropriate, local NHS service providers can use to attach to their stock that is showing that it is due to expire soon. There continues to be sufficient supply available which can be ordered through the usual routes.

Kind regards

Danny

Danny Palmer

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From: Recovery Trial <recoverytrial@ndph.ox.ac.uk>

Sent: 29 November 2022 09:44

To: Recovery Trial <recoverytrial@ndph.ox.ac.uk>; Danny Palmer <Danny.Palmer@uhbw.nhs.uk>;
Marjia.Monsur@dhsc.gov.uk; Richard Haynes <richard.haynes@ndph.ox.ac.uk>

Subject: RECOVERY molnupiravir & paxlovid use summary

Dear Colleagues

Please find attached the weekly summary of molnupiravir & paxlovid use per site.

Have a lovely week!

Best Wishes

Wojtek

Wojciech Brudlo

Clinical Trial Administrator

RECOVERY Trial

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