
From: HEALEY, Frances (NHS ENGLAND & NHS IMPROVEMENT - X24) [I/S]
Sent: 3/17/2022 8:39:45 AM
To: [I/S] (NHS ENGLAND & NHS IMPROVEMENT - X24) [I/S]
Subject: [I/S] FW: background review
Attachments: DO NOT CIRCULATE PRINT OR CASCADE NRLS review oxehealth & oxevision for MHRA 01Sept2021.pdf

Frances

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From: HEALEY, Frances (NHS ENGLAND & NHS IMPROVEMENT - X24) [I/S]

Sent: 10 February 2022 13:00

To: [I/S] (NHS ENGLAND & NHS IMPROVEMENT - X24) [I/S]; [I/S] (NHS ENGLAND & NHS IMPROVEMENT - X24) [I/S]; [I/S] (NHS ENGLAND & NHS IMPROVEMENT - X24) [I/S]; [I/S] (NHS ENGLAND & NHS IMPROVEMENT - X24) [I/S]

Subject: background review

Hi all

Thanks so much for call and I think more time is worthwhile.

Attached might help in meantime, [I/S] already has – not for forwarding because of MHRA sensitivity. Whilst carefully couched in the attached, Oxehealth team in the MHRA discussion confirmed that what we teased out there in terms of what it actually technically does appears to be correct.

As discussed I think it does legitimate good things, problem is risk created by any hype or misunderstanding that makes even a very few patients or staff believe it will do something more.

MHRA zone broadly relates to correct description of purpose of a medical device and appropriate Instructions for Use, which does cover a lot of the concern. For longer term safety getting the right advice to users much more likely if MHRA can encompass within regulation (though I made a strong pitch to Oxehealth to look at their website with fresh eyes out of good conscience, can't see any changes since).

In very simple terms my understanding of the boundary of MHRA zone is when something is a medical device, you can only describe it doing what it is registered to do but they won't get into how effective it is at doing so (that is expected to be a clinical effectiveness assessment users/guideline issuers make). Or to put it another way, MHRA extremely good and strong at making sure a medical device is described as suitable for a particular use and doesn't do harm, but doesn't get into whether it does good. Oxehealth is part medical device (the part that takes pulse and respiration) and partly not medical device (everything else) but if the other parts have a clinical use it may need to be registered as a medical device. I believe falls prevention alarms for hospital use that alert when the patient stands would be expected to register as medical devices, but devil may be in the detail in terms of whether these are claims made by manufacturer for how it can be used or information on how people have used it, and I'm not sure if any precedent for medical devices to prevent self-harm.

MHRA won't get into issues of consent, and of course consent (or best interests) relies on being able to clearly explain benefits, so I think would be a positive step forwards not treading on MHRA's toes to develop those leaflets. Suspect you'd need separate versions/sections for falls versus self-harm and seclusion room obs uses.

All best

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