From the Chief Medical Officer
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FOR ACTION
Chief Executives, Public Health Agency/Health and Social Care Board/HSC Trusts/ NIAS
Chief Executive, BSO
GP Medical Advisers, Health & Social Care Board
All General Practitioners and GP Locums *(for onward distribution to practice staff)*
OOHs Medical Managers *(for onward distribution to staff)*

PLEASE SEE ATTACHED FULL CIRCULATION LIST

Dear Colleague

UK PATIENT SAFETY ALERT NatPSA/2021/005/MHRA- Philips ventilator, CPAP and BiPAP devices: Potential for patient harm due to inhalation of particles and volatile organic compounds

ACTION

HSC Trust Chief Executives are asked to:

- Appoint an Executive Director to oversee the actions required in response to this alert.
- Disseminate this alert to all relevant staff.
- Nominate a representative to join the short life working group to agree and develop the response across the region as required.

BSO Chief Executive:

- Nominate a procurement lead to join the short life working group to agree and develop the response across the region as required.

HSCB/PHA Chief Executives:

- Nominate a quality and safety lead to co-chair the short life working group to agree and coordinate the response across the region as required.
- Consider the NaPSA alert through the normal HSCB/PHA processes for assuring implementation of safety and quality alerts.

SUMMARY

As you may already be aware Philips issued two Field Safety Notices (FSN) on the 21st June 2021 to highlight the potential harm to patients from use of certain respiratory devices used in patients with either Obstructive Sleep Apnoea (OSA) or respiratory failure. There is a risk of patient harm from degradation of the sound abatement foam found in these devices. Advice to specialist clinicians who commence and review patients on treatment with these devices is to risk assess the benefits for continued use for patient treatment against the risks identified.

The Medicines and Healthcare products Regulatory Agency (MHRA), as the UK regulator for medical devices, in support of the FSNs, issued the UK Patient Safety Alert NatPSA/2021/005/MHRA with the recommended actions to be undertaken so that safety of patients is not compromised (Annex 2). **These actions should be assessed and implemented as part of your organization's initial response to this alert**.

There are more than 5,000 affected devices in use in Northern Ireland. As this issue affects devices worldwide, it will not be possible to find replacements on this scale; nor is repair by Phillips likely in the short to medium term. Both the Field Safety Notice and the MHRA information advises that **patients should continue to use these products unless otherwise advised by their clinician.**

In order to coordinate a regional response to this issue I have asked the Public Health Agency (PHA) to establish a short life working group to review the MHRA alert and the actions required, the potential risk to patients from the continued use of the devices, the identification of alternative product where risk is/would be deemed unacceptable and how communications to patients will be handled. It is expected that there will be a demand on alternative devices for new prescriptions, therefore the group will consider all options for ensuring the safe continued provision of care in this evolving situation.

BACKGROUND

There are two identified issues:

1. Degradation of foam causing potential for particles to be inhaled or ingested. There have been a small number of reports outside the UK of this causing minor, short-term effects such as: irritation to the skin, eye, and respiratory tract; an inflammatory response; headaches; asthma. Inappropriate use and decontamination methods can worsen the foam degradation.

2. Release of volatile organic compounds (VOC) including Dimethyl diazene and Phenol. Evidence suggests these gases dissipate after 24 hours from first 'out of box' use.

There is a risk of short-term effects such as: headache/dizziness; irritation of the eyes, nose, respiratory tract and skin; hypersensitivity; nausea and vomiting. There have not been any reports of this to date.

Patients with known allergies or sensitivities to these VOCs should be prioritised for an alternative device if available. There are currently no definitive data showing long-term harm to patients, but VOCs and degradation of the foam are potentially associated with possible long-term effects such as: genotoxicity; mutagenic and carcinogenic effects; hepatotoxicity; nephrotoxicity; neurotoxicity.

No adverse events in the UK in relation to these devices have been reported to the MHRA. From a clinical perspective, the risk of discontinuing therapy for the vast majority of patients far outweighs continuing therapy until a replacement device can be sourced. For most patients this means they should continue to use their device as normal.

However as per item 2 above for patients with certain very rare forms of occupational asthma related to isocyanates an alternative device should be provided. This action is being recommended out of an abundance of caution.

As a result of this issue Philips will pause shipping these products to the Health Service. BSO PaLS is working to source alternative products both to allow for patients that need to exchange their devices for clinical purposes and for new patients who need to start PAP therapy.

CURRENT NI POSITION

The Department along with colleagues in the Business Service Organization's Procurement and Logistics Service (BSO PaLS), the Public Health Agency and local respiratory consultants have been engaging with colleagues across the UK on this issue, as well as assessing the likely impact of this National Patient Safety Alert and the Field Safety Notices to the HSC.

There are a significant number of these devices in use in Northern Ireland. It is understood that the majority of the devices in use are on a managed service contract with the supplier. However a number of devices have also been directly purchased by HSC Trusts and private customers. BSO PaLS is liaising with the supplier on the location of these devices in NI, to assist your response.

Nationally a patient information leaflet is being prepared and an expert group has been convened to inform the risk assessment. This information will be shared shortly with the local regional working group.

Enquiries:

Any enquiries about the content of this letter should be addressed to:

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Yours sincerely

PROFESSOR SIR MICHAEL McBRIDE
Chief Medical Officer

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