From the Chief Medical Officer
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HSS(MD)24/2021

Our Ref: HSS(MD)24/2021
Date: 16 March 2021

FOR ACTION
Chief Executives, Public Health Agency/Health and Social Care Board/HSC Trusts/NIAS
GP Medical Advisers, Health and 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 Colleagues

UK PATIENT SAFETY ALERT NATPSA/2021/001/MHRA - BECTON DICKINSON (BD) INTRA-VENOUS (IV) AND GRAVITY FEED INFUSION SETS

ACTION

HSC Trust/NIAS 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 chair the short life working group to agree and develop 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 Becton Dickinson (BD) issued a Field Safety Notice (FSN) on the 11 March 2021 to recall certain distributed lots of their Intra-Venous (IV) and gravity feed Infusion Sets (Annex 1). This FSN advises users of these sets to stop their use with immediate effect. The immediate cessation of use of these sets may place acute pressure on some HSC Trusts and creates an UK supply issue along with potential clinical care risks to patients.

The Medicines and Healthcare products Regulatory Agency (MHRA), as the UK regulator for medical devices, in support of the FSN, issued the UK Patient Safety Alert NatPSA/2021/001/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 organizations initial response to this alert**. Please ensure that a clinical risk assessment is undertaken for products where the clinical risk of an immediate withdrawal is greater than the risk of their continuing use.

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 current risks relating to the immediate stock of the items involved, the potential risk to patients from the continued use of BD product, and the identification of alternative product where risk is/would be deemed unacceptable.

This working group will also examine the care settings and clinical processes using the affected BD products, and it will consider all options for ensuring the safe continued provision of care in this evolving situation.

BACKGROUND

Becton, Dickinson and Company (commonly known as BD) is an American multinational medical technology company that manufactures and sells medical devices, instrument systems and reagents to health care institutions, clinical laboratories and the general public.

BD provides infusion sets, gravity sets and connectors to the NHS, the HSC and worldwide. They have been notified that a 3rd party sterilisation services provider, whom they contract to sterilise their products, has intentionally falsified sterilisation process records related to the processing of their products.

BD immediately conducted an investigation and has determined that it is unable to guarantee the sterility of a number of IV infusion set devices that are used with their range of pump-sets. BD, in line with required regulatory action, is now removing these products from the market.

BD is taking urgent steps for a new sterilisation plant to be certified. It is currently expected that new product will be available from the end of March 2021.

BD has not identified any reports of adverse events or serious patient harm to date that could be associated to the field safety corrective action and there are no specific patient follow-up activities required where the product has already been used.

CURRENT NI POSITION

The Department along with colleagues in the Business Service Organization's Procurement and Logistics Service (BSO PaLS) have been assessing the likely impact of this National Patient Safety Alert and FSN to the HSC. The infusion sets affected are the compatible product for use with the Alaris range of volumetric pump sets that are in widespread service across the UK as a whole and within two HSC Trusts in Northern Ireland.

BSO PaLS has advised that they have adequate supply of BD high volume stock items at their warehouse that will ensure supply where clinical risk arising from discontinued use is deemed to be greater than the risk of ongoing use.

With regard to non- stock items the Department and BSO PaLS, along with colleagues in the Department of Health and Social Care London (DHSC) and the MHRA, are liaising with BD to secure continued supply where clinical risk requires its use.

BSO PaLS is also liaising with the DHSC regarding the potential for supply of alternative products from BD. The outcome of this work will be advised to the short life working group. Please note that as this is a major supply disruption across the UK that the call on alternative products may outstrip supply.

Enquiries:

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

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Yours sincerely

DR MICHAEL McBRIDE
Chief Medical Officer

Circulation List

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