NHS Pharmaceutical Aseptic Services Group

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PASG Interim Neuraxial Device Guidance Issued Pending Final Assessment of Device Manufacturer's Test Data for Drug Storage in NRFit™ / ISO 80369-6 Neuraxial Syringes

This statement has been issued to NHS Pharmacy Aseptic Units in response to concerns and questions raised about the current situation relating to NRFit™ / ISO 80369-6 Neuraxial Devices, and the continued availability of Surety® devices within the NHS.

The latter predominantly relates to England where Surety® devices have been widely used to prevent patient safety issues during neuraxial procedures – intrathecal (spinal), epidural & regional routes of administration. The other home nations have continued to use Luer connectors until ISO standard devices became available in the UK. However, the issues relating to drug storage in the new ISO 80369-6 devices apply to the NHS in the UK as a whole.

1) The continued availability of Surety® syringes etc. during the transition and switchover to NRFit™ – NHSI issued a Patient Safety Alert - resources to support transition to NRFit in August 2017. This has raised some concern amongst Trusts in England that supplies of Surety® devices will run out before they can safely switch to NRFit™ devices for all their neuraxial procedures, including intrathecal chemotherapy. However, ongoing discussions are taking place to clarify the actual supply chain situation with Surety® devices. GBUK (who took over Intervene in 2016) are working with NHS Supply Chain to monitor and manage stock levels to ensure continued availability over the coming months. Should you be unable to access product through NHS Supply Chain then you should contact GBUK, as they may be able to meet requirements directly. The only exception where there is definitely no Surety® stock available is the Ommaya reservoir kit, which has affected a small, but nevertheless critical, number of neurosurgery centres who have had to revert back to Luer access devices (recorded in their Trust risk registers where determined as necessary following local risk assessment) until they can safely switch to NRFit™.

2) Test data for NRFit™ syringes & caps – Information about the NHS Pharmacy testing requirements & protocols for these devices can be found on the open part of the PASG website here . GBUK have undertaken this testing, but have decided to make their primary test reports available to the NHS only under a confidentiality agreement. Their data is currently being scrutinised by an expert NHS colleague. Once this is complete and any outstanding issues have been resolved, a statement for NHS Pharmacy Aseptic Services will be issued confirming the maximum shelf-life that can be assigned to products stored in GBUK NRFit™ syringes i.e. intrathecal chemotherapy and epidural drugs, without the need to conduct further in-house testing. GBUK have issued their own statement or 'Declaration of Conformity' in a letter dated 28.09.17, but PASG would urge you to wait for the NHS statement to be issued.

There is a second device manufacturer, BBraun, also producing NRFit™ syringes and currently conducting the same tests against the same protocols. Results from BBraun aren't available yet, but they are expected to be ready for review during November. The intention is that these results will also be scrutinised and a similar NHS statement for Pharmacy Aseptic Services will be issued once any outstanding issues have been resolved, confirming the

maximum shelf-life for products stored in BBraun NRFit™ syringes without the need to conduct further in-house testing.

3) Deployment guidance for NRFit™ Devices - Information about deploying the new ISO standard neuraxial devices within the NHS, with particular reference to pharmacy issues, can also be found on the open part of the PASG website here . Some of the timelines have slipped since this paper was written which is outside our control.

Overall, for intrathecal chemotherapy, and drugs for epidural & regional use prepared in pharmacy aseptic units, the PASG advice remains to wait until the syringe storage test data is complete, and NHS statements in relation to the companies' devices have been issued before switching to NRFit™ devices.

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