

## Frequently Asked Questions – Ultrasound Gel

### **1. Why has the sale of these three products been suspended by NHS Supply Chain?**

NHS Supply Chain always takes action to ensure the safety of users and patients. In this case, it was deemed prudent to suspend sales on that basis, whilst the outstanding investigations and testing are conducted by system partners, led by Public Health England. We have taken similar action before, with other products, as part of our increasing quality and safety focus.

### **2. What are the alternative products available through NHS Supply Chain?**

The alternative products are being communicated in our Important Customer Notice, including specifying the dates from which they are available for NHS organisations to order. The link is here:

<https://www.supplychain.nhs.uk/icn/public-health-england-good-infection-prevention-using-ultrasound-gel-practice-guidance/>

As new products become available, the Important Customer Notice will be updated with that information to ensure our customers are clear on what they are able to order and when.

### **3. When will those products become available?**

As new products become available, the Important Customer Notice will be updated with that information to ensure our customers are clear on what they are able to order and when.

<https://www.supplychain.nhs.uk/icn/public-health-england-good-infection-prevention-using-ultrasound-gel-practice-guidance/>

### **4. Are you working on providing additional alternatives in the short term to meet our future supply/volume needs?**

Yes. NHS Supply Chain buyers are experienced in working with suppliers and distributors to meet the needs of our customers. They are able to work at pace where we require this to source additional supply lines of appropriate products to meet user and patient need. This procurement activity is currently underway in relation to ultrasound gel to ensure we can meet the demand needs of NHS Supply Chain's customers.

### **5. Are you recalling stock of these products which have already been bought?**

Currently there are no plans to recall the stock. The products already purchased should be used in accordance with the PHE guidance which can be found here:

<https://www.gov.uk/government/publications/ultrasound-gel-good-infection-prevention-practice>



**6. How will you keep us up to date about changes that are being made to the products available from NHS Supply Chain?**

We will continue to issue Important Customer Notices to update on the position of the products suspended from sale and alternative products.  
We will also continue to update these Frequently Asked Questions.

**7. What is the role of Public Health England in this issue?**

PHE exists to protect and improve the nation's health and wellbeing and is responsible for investigating and mitigating incidents which pose a potential threat to public health. PHE is currently undertaking some testing of ultrasound gels and together with NHSEI and MHRA informs actions taken by NHS Supplies.

**8. What is the role of the MHRA in this issue?**

The Medicines and Healthcare products Regulatory Agency (the MHRA) is the authority for regulation of medical devices in the UK. Non-sterile ultrasound gel used in the diagnosis and treatment of patients across the UK is a class I medical device.

The MHRA ensures manufacturers meet relevant regulatory standards for placing on the market and supplying medical devices, including post market surveillance and vigilance. We are working with the MHRA as part of discussing next steps on these products from a regulatory perspective as well as from a public health and NHS Supply Chain safety perspective.

**9. What is the role of NHSEI in this issue?**

NHSEI is the national body setting policy and standards for the English health and social care system including for infection prevention and control.

**10. Has NHSEI issued communications also?**

The NHSEI IPC Team has issued communication to Chief Nurses advising of the issues with the affected products and adherence to the Public Health Guidance when using retained stock in the system. The Guidance is here:

<https://www.gov.uk/government/publications/ultrasound-gel-good-infection-prevention-practice>

**11. Is NHS Supply Chain engaged with British Medical Ultrasound Society or other professional organisations on this issue?**

Yes, we are engaged with the Society and ensuring they have clarity on the NHS Supply Chain position both now and as this develops, including in relation to increasing our offer of alternative products whilst the suspension of the affected products remains in place.

**12. Is NHS Supply Chain in close communication with PHE, NHSEI and MHRA?**



Yes, we are working in partnership on the safety of these affected products, but also on the wider safety agenda to ensure our own systems, policies and processes are able to respond to their requirements, and so we can take decisive action in response to their decisions as well as our own.

**13. When will these products become re-available for purchase?**

The products will only become re-available for purchase once the NHS Supply Chain, as a result of the work underway by PHE and subject to any further engagement with MHRA and NHSEI, is confident of their safety for users and patients.

**14. What about products I am buying from other sources? Are they safe? How do I confirm this with you and the healthcare system?**

The safety of medical devices on the UK market is assured by the regulatory process overseen by the MHRA. Validly CE marked devices have been demonstrated to be safe when used as intended, queries and enquiries should be sent to MHRA, Yellow Card scheme  
Alternatives that are purchased through NHS Supply Chain or directly through suppliers will need to be used in accordance with the PHE guidance.

**15. How can I propose possible alternatives for purchase which you may not be aware of?**

Please email possible alternatives to the Patient Safety email:  
[patient.safety@supplychain.nhs.uk](mailto:patient.safety@supplychain.nhs.uk)

We will ensure that relevant buyers are advised of potential alternative products.

**16. Will there be a 5 litre alternative as well as the 250ml?**

Currently, there are no other manufacturers of the 5L cannisters. This may become available at a future date and we will advise via a future Important Customer Notice.

**17. Is this specific to a non-sterile and single use bottle?**

The suspended products are the non-sterile products which come in 20g sachets, 250ml bottles and 5L cannisters. The 20g sterile product can still be purchased via NHSSC.

**18. How is this different from other non-sterile single use gel bottles on the market such as 'Aquasonic 100' manufactured by Parker, which is recommended by many of the ultrasound system manufacturers I work with?**

NHS Supply Chain has suspended 3 codes due to their potential safety impacts and alternatives in use, or being made available via the NHS Supply Chain, are deemed safe for use in association with the PHE guidance on the use of ultrasound gel.

The Guidance can be found here:



<https://www.gov.uk/government/publications/ultrasound-gel-good-infection-prevention-practice>

**19. Does the recommendation to use this particular ultrasound gel now render stocks of other single use gel bottles unsafe?**

No, the stock should be safe to use if the PHE guidance is followed. This guidance includes instruction on when to use sterile and non-sterile gels, safe use of these gels and good practice when using reusable bottles. The guidance can be found here:

<https://www.gov.uk/government/publications/ultrasound-gel-good-infection-prevention-practice>

**END**

