Office for Product Safety & Standards

Office for Product Safety and Standards

4th Floor Multistory 18 The Priory Queensway Birmingham B4 6BS

Miss Isobel Thistlethwaite
HM Assistant Coroner, Rutland and North Leicestershire
Rutland and North Leicestershire Coroners Court,
County Hall,
Glenfield
LE3 8RA

6 November 2025

Dear Miss Thistlethwaite

I am the Deputy Chief Executive for Regulation at the Office for Product Safety and Standards (OPSS), responding to your Prevention of Future Deaths report into the fatality of 72-year-old Susan Lakin, involving an ORTONES support belt for wheelchairs and armchairs. I was very sorry to hear of this tragic fatality, and if you have the opportunity, please pass on my condolences to Mrs Lakin's family.

As explained in their response to your report, the Medicines and Healthcare products Regulatory Agency (MHRA) informed OPSS of this case earlier in the year and shared details regarding the circumstances of Mrs Lakin's death, the product involved and the businesses identified. Since being made aware, OPSS has taken a range of actions in relation to these and similar products, which I have set out below.

OPSS has confirmed the position advised by MHRA that the ORTONES Wheelchair and Geriatric Armchair Belt Restraint is not in scope of the healthcare products regulatory regime, and is instead covered by the General Product Safety Regulations 2005 (the 2005 Regulations). The 2005 Regulations require businesses to ensure that consumer products placed on the UK market are safe, and that potential risks associated with their use have been mitigated or reduced as far as possible. This includes by providing appropriate instructions for safe use, information about restrictions on use, and any relevant warnings. The 2005 Regulations apply where there are not sector specific regulations.

OPSS can confirm that the relevant businesses (the manufacturer, Eurobaston, and Comercial Nespral, the distributor of the product in the UK), have undertaken the following corrective action to address the risks posed by the products:

- provided updated information in the instructions regarding the product's potential risks, and issued this to customers who had already purchased the product;
- removed the product from sale via Amazon;
- withdrawn the product from the UK market.

The distributor submitted a product notification to OPSS as required by Regulation 9 of the GPSR. This publicises the risk posed by the product and the mitigating actions taken by the manufacturer.

These steps should ensure the product is no longer available to purchase in the UK. On 31 October, OPSS published a product safety report for the ORTONES belt on the Product

Recalls and Alerts <u>gov.uk website</u>, to raise awareness of consumers, businesses and other regulators to this product's risks, and the corrective action taken by the business.

Alongside the steps to reduce the risk to consumers posed by the ORTONES belt, OPSS has been gathering wider intelligence into wheelchair/armchair support belt products. There is a broad range of similar support belts and harnesses available to UK consumers, supplied via online marketplaces and by specialist retailers. This review did not find any evidence of product safety concerns raised by Trading Standards or Citizens Advice, and OPSS had not received notifications about support belts to our Product Safety Database from other regulators.

However, OPSS noted that the MHRA recorded 29 medical incidents involving these product types since 2014, resulting in one fatality and 20 injuries. We also found that the British Standards Institution referred to four fatalities in the 15 years prior to introducing the relevant product standard BS EN 8625:2019. Further, in our research into similar products available on the market today, OPSS established that certain items, intended to aid people who may have mobility or strength impairments, were accompanied by instructions for safe use that require levels of physical ability that might be beyond people with such impairments. These products may not be safe if used without help or supervision, but many products did not carry reasonable warnings to raise awareness of, or address, this risk.

On this basis, OPSS is taking further action on this product category. We have written to major online marketplaces, including Amazon, eBay, Temu, Shein and Alibaba, to make them aware that certain products may not be provided with suitable instructions or warnings to assure safe use by likely users. This will assist online marketplaces to identify whether these products are available on their platforms and take action to update or remove relevant listings. OPSS has also alerted online marketplaces to our Product Safety Report published for the ORTONES belt to make clear this product should not be supplied. OPSS has highlighted our activity for these products to relevant stakeholders, including Age UK and the Royal Society for the Prevention of Accidents.

OPSS is continuing to monitor the available evidence and engage with retailers and manufacturers in the UK, to ensure products are supplied with clear and appropriate instructions and warnings and do not pose a risk when they are used normally and foreseeably.

I hope this information is helpful and provides evidence of OPSS's commitment to protecting consumers, following your Prevention of Future Deaths report into the tragic death of Mrs Lakin. I would be grateful, should you have the opportunity, if you would share this with the family.

Kind regards,



Deputy Chief Executive – Regulation
Office for Product Safety and Standards