



Medicines & Healthcare products Regulatory Agency

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Professor Henrietta Hughes
Patient Safety Commissioner
By Email: Henrietta.Hughes@patientsafetycommissioner.org.uk

Reference: CEO 20358

2 May 2025

Dear Henrietta,

The Safety Gap - Report Publication

Thank you for our recent meet and for your email of 31 March 2025, enclosing your landmark report, *The Safety Gap*.

It is great to have the opportunity to comment on, and contribute to, the main body of *The Safety Gap*. This is an important topic and we are committed to ensuring that people with sensory impairment can reliably access information about medicines they use. The Report includes two recommendations which are particularly pertinent to the work of the MHRA.

Recommendation 1: The MHRA needs to review – working alongside patients – whether their current guidance and regulations for the licencing and packaging of medicines goes as far as is possible to enable their safe use by those with sensory impairment.

Recommendation 2: The ABPI, MHRA and DHSC should work together to restart work – alongside published milestones – to digitise paper-based patient information leaflets via the existing UK Electronic Patient Information Task Force (ePIL – electronic patient information leaflet). As part of this restart, ePIL – working with patients – should examine how to maximise the benefits of this work for patients with sensory impairment.

On **Recommendation 1**, I understand that labels and leaflets accompanying licenced medicines must meet the current legislative requirements for those with sight loss, including the product name in braille on the carton and provision of the leaflet in the format requested by the patient. However, there is opportunity to improve information based upon user research to ensure this fulfils the need of this patient group and others. The current Agency

Business Plan includes the recommendation to review options for optimising information for all patients and carers.

On **Recommendation 2**, our refreshed Business Plan (2025-2026) includes a commitment to scope and engage with healthcare partners to identify opportunities to enable better patient access to healthcare information. The Agency will be reviewing options to ensure suitable electronic formats can be enabled for people with sensory impairment. A meeting with the ePI Taskforce is already scheduled. The review will include looking at improving access to medicines information for all patients.

I will ensure colleagues across the Agency keep you updated you on our progress against these recommendations. Please do not hesitate to let me know if you would like to discuss further.

Best wishes,

A handwritten signature in dark ink, appearing to read 'Lawrence Tallon', written in a cursive style.

Lawrence Tallon
Chief Executive
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