

39 Victoria Street London SW1H 0EU

Our ref:

Dr Shirley Radcliffe, HM Assistant Coroner, East London Coroner's Office Queens Road Walthamstow, E17 8QP

By email:

15 October 2024

Dear Dr Radcliffe,

Thank you for the Regulation 28 report of 20 August 2024 sent to the Secretary of State at the Department of Health and Social Care (DHSC) and to the Secretary of State for Education about the death of Hannah Jacobs. I am replying on behalf of both Secretaries of State as I am the Minister in DHSC with responsibility for long-term conditions, including allergies. In preparing this response, my officials have liaised with the Department for Education (DfE), the Medicines & Healthcare products Regulatory Agency (MHRA) and NHS England.

Firstly, I would like to say how saddened I was to read of the circumstances of Hannah's death, and I offer my sincere condolences to her family and loved ones. Hannah's loss at such a young age must be extremely distressing for them and I am grateful to you for bringing these concerns to my attention.

Your report raises concerns over:

- A lack of consideration about how to contain the risk of anaphylaxis on the journey to and from school.
- The lack of a readily available adrenaline autoinjector (AAI) especially where they are misused, lost or forgotten, leaving an absence of an AAI over the weekend.
- The need for appropriate structures in place to educate schools, patients and parents of the importance of carrying an AAI on their way to and from school.

I also understand that in a separate report that you have issued to NHS England, you raised concerns about supplies of AAIs as the pharmacy at which Hannah and her mother attempted to obtain an EpiPen did not have any adult doses in stock and, by that point, Hannah required two doses from an adult EpiPen.

On the issue of educating patients parents and schools, the message to use an AAI at the first signs of a severe reaction before calling for help, and the recommendation for patients to carry two AAIs has been reinforced through a series of advice and guidance.

In June 2023, the MHRA launched new guidance to highlight the latest safety advice from the Commission on Human Medicines (CHM's) working group on the safe and effective use of AAIs. The guidance included advice for healthcare professionals to provide to patients and carers and reinforces the importance of carrying 2 AAIs at all times, and using AAIs without delay if anaphylaxis is suspected, even if in doubt about the severity of the event. The guidance can be accessed at the following link:

https://www.gov.uk/government/publications/adrenaline-auto-injectors-aais-safety-campaign/adrenaline-auto-injectors-aais

The MHRA has also produced a toolkit of resources which is available for health and social care professionals to support the safe and effective use of AAIs. These resources are freely available and include an infographic about the correct use of an AAI. Health and social care professionals are asked to use the materials to inform patients and caregivers what to do if they suspect anaphylaxis and how to use AAIs and that prescribers should prescribe two AAIs to make sure that patients always have a second dose. The resources are available at the following link:

## https://aaisafety.campaign.gov.uk/resources/

The information set out in the guidance remains current and we have been advised by MHRA that there are currently no plans to revise it. MHRA continues to signpost the public, media and charities to the guidance to encourage safe use of AAIs wherever possible.

Information is also contained in the British National Formulary (BNF) and the BNF for children (BNFc), that patients should carry two AAI devices (AAI) at all times; on the importance of training as well as on the importance of training patients and carers in the use of the particular AAI prescribed. The BNF and BNFc are joint publications of the British Medical Association and the Royal Pharmaceutical Society and are accessible from the National Institute for Heath and Care Excellence's (NICE) website. The information referred to above can be found at:

## https://bnf.nice.org.uk/drugs/adrenaline-epinephrine/#important-safety-information

Prescribers are expected to refer to information within the BNF to help inform prescribing decisions made with Individual patients and carers. This expectation is set out in the GMC's publication on 'Good practice in prescribing and managing medicines and devices', which I have referred to above, within the section titled: keeping up to date and prescribing safely. This section can be found at the following link:

https://www.gmc-uk.org/professional-standards/professional-standards-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/keeping-up-to-date-and-prescribing-safely.

Advice on preventing anaphylaxis is provided on the NHS.UK website and this also recommends that patients carry two AAIs with them at all times. The advice can be accessed at the following link:

https://www.nhs.uk/conditions/anaphylaxis/#:~:text=Immediate%20action%20required%3A %20Call%20999%20if%3A&text=your%20skin%2C%20tongue%20or%20lips,and%20can not%20be%20woken%20up

Section 100 of the Children and Families Act 2014 places a legal duty on schools to make arrangements for supporting pupils at their school with medical conditions. The accompanying statutory guidance - Supporting Pupils at School with Medical Conditions - is not voluntary; schools are legally required to have regard to this guidance when carrying out their section 100 duty.

The guidance makes clear to schools what is expected of them in taking reasonable steps to fulfil their legal obligations and to meet the individual needs of pupils with medical conditions, including allergies. Schools should ensure they are aware of any pupils with medical conditions and have policies and processes in place to ensure these can be well managed.

The guidance can be accessed at the following link:

https://www.gov.uk/government/publications/send-code-of-practice-0-to-25

DfE included a reminder to schools of these duties in its regular schools' email bulletin in both March and September this year. Copies of the bulletin are available here:

March 2024 - <u>Update to all education and childcare settings and providers</u> (govdelivery.com)

September 2024 - <u>Update to all education and childcare settings and providers</u> (govdelivery.com)

In the same communication DfE also alerted schools to the newly created Schools Allergy Code. The Code was developed by The Allergy Team, Independent Schools' Bursars Association (ISBA) and the Benedict Blythe Foundation, who are all trusted voices on the matter of allergies. DfE has now also added a link to the Code to its online allergy guidance on Gov.uk. The Code can be accessed at the following link:

https://theallergyteam.com/schools-allergy-code/

In 2017, the Department of Health published non-statutory guidance to accompany a legislative change to allow schools to purchase spare AAIs from a pharmacy, without a prescription and for use in an emergency situation. This guidance gives clear advice to schools on the recognition and management of an allergic reaction and anaphylaxis, and outlines when and how an AAI should be administered for pupils in schools. The guidance states that children at risk of anaphylaxis should have their prescribed AAIs at school for use in an emergency, and in line with MHRA advice, those prescribed AAIs should carry two devices at all times. The guidance also states that depending on their level of understanding and competence, children and particularly teenagers should carry their AAIs on their person at all times or they should be quickly and easily accessible at all times. I understand that it is not uncommon for schools, particularly primary schools, to request a pupil's AAIs are left in school to avoid the situation where a pupil or their family

forgets to bring the AAIs to school each day. Where this occurs, the guidance states that the pupil must still have access to an AAI when travelling to and from school.

*'Guidance on the use of adrenaline auto-injectors in school'* can be accessed through the following link and DHSC keeps the guidance under review.

https://assets.publishing.service.gov.uk/media/5a829e3940f0b6230269bcf4/Adrenaline\_au to injectors in schools.pdf

An Expert Advisory Group for Allergy (EAGA) has been established, which brings together key stakeholders with the aim improving the quality-of-life of people with allergies. Chaired jointly by DHSC and the National Allergy Strategy Group, EAGA identifies priority areas for DHSC, NHS England and other government departments and agencies relating to allergy that require policy change or development and advises on how to best achieve improved outcomes and improve support for people with allergies.

In relation to shortages of AAIs, DHSC works closely with all suppliers of AAIs to ensure supplies remain available for patients. We understand that in February 2023 all suppliers of adrenaline 0.3mcg auto-injectors were in stock, including EpiPen. One supplier of 0.15mcg had been out of stock since early 2020 but the remaining two suppliers, including EpiPen, were available in sufficient quantities to support patient demand. The sole supplier of the 0.5mcg pen (Emerade) was also in stock during this time.

Officials continue to work with MHRA, the pharmaceutical industry, NHS England and others operating in the supply chain to help prevent shortages and to ensure that the risks to patients are minimised when shortages do arise.

I hope this response is helpful in demonstrating the ways in which your concerns are being addressed and will continue to be addressed. Thank you for again for bringing to the attention of the Secretaries of State and their respective departments the concerns that have followed the inquest into the tragic death of Hannah Jacobs.

Yours sincerely,