Department of Health & Social Care

From the Lord Bethell
Parliamentary Under Secretary of State for Innovation

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[redacted]

Our Ref: [redacted]

Dr Andrew Harris
HM Senior Coroner, London Inner South
HM Coroners Court
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16 April 2021

Dear Dr Harris

Thank you for your letter of 18 December 2020, received by this Department on 6 January 2021, to Matt Hancock about the death of Ruben Bousquet. I am replying as Minister with policy responsibility for medicines and medical devices and I am grateful for the additional time in which to do so.

Firstly, I would like to say how deeply saddened I was to read of the circumstances of Ruben's death. I can appreciate how distressing his death must be for his parents and those who knew and loved Ruben and I offer my heartfelt condolences. It is vital that we take the learnings from what happened to Ruben to prevent future deaths.

Reporting and Registering

As articulated in your report, these matters of concern refer firstly to consideration of the establishment of a national reporting system to enable local authorities and the Food Standards Agency (FSA) to access data; and secondly, the maintenance of a fatalities register to determine the circumstances of these deaths.

As you are aware, currently the FSA has no means to access data on allergic reactions. The FSA is undertaking work to establish a way for people to directly report information regarding anaphylactic reactions caused by food allergies that do not result in death. We understand that the FSA is considering how to collect more information on allergic reactions and is undertaking consumer research to gather information and insights from people with food allergies. This intelligence will help the FSA build a better picture of the emerging patterns on allergic reactions experienced by consumers.

We agree that it is essential that we learn from these tragedies. In conjunction with the FSA's ongoing programme to collect more information on allergic reactions, the Department of Health and Social Care is working to support the FSA to increase information prevalence regarding such fatalities.

Furthermore, officials from the Department and the FSA are together considering the existing data available from across the medical estate on food-related anaphylaxis cases, and how this might be analysed and used to prevent future incidents and deaths. The intention is to understand what more both Departments are able to do in this area.

I am aware that the FSA has provided you with a more detailed response on these matters, as well as supporting information on its strategy on food hypersensitivity, which the Department fully supports. I hope that information is helpful to you.

Availability of emergency Adrenaline Auto-injector (AAI) devices in the retail food sector

In relation to your second matter of concern regarding the availability of emergency Adrenaline Auto-injector (AAI) devices in the retail food sector, my officials have liaised with the Medicines and Healthcare products Regulatory Agency (the MHRA), which is responsible for the regulation of medicines in the UK.

I can assure you, and Ruben's family, that making AAI devices more widely available for use in exceptional, emergency situations, is being considered carefully and thoroughly.

The MHRA is providing a detailed response to you on the work that is taking place to consider and respond to a range of issues relating to the safe and effective use of AAIs. This includes a recommendation in principle by an Expert Working Group on AAIs (EWG AAIs), endorsed by the UK Commission on Human Medicine (the MHRA's independent scientific advisory committee), that AAIs should be made available in public locations for use to treat anaphylaxis in unforeseen, critical circumstances, provided that safeguards can be implemented to ensure effective and safe use. Cinemas offering food for sale is an example of the type of location that the EWG AAIs identified as having particular potential to save lives.

The EWG AAIs made a number of other recommendations including the reinforcement of critical safety measures to patients on the use and management of AAIs.

A report summarising the conclusions and recommendations of the AAI EWG, endorsed by the UK Commission on Human Medicine, is expected to be published by the end of May 2021.

Further work is required to consider the full implications of this recommendation, including how widening access to AAIs for emergency use can be safely implemented, as well as the need for legislative change.

I hope this response is helpful and demonstrates our continued commitment to ensure the safety of those with food-related allergies. I am grateful to you for bringing these concerns to my attention.

LORD BETHELL