Medicines & Healthcare products Regulatory Agency

MHRA

HM Senior Coroner Dr Andrew Harris
Southwark Coroner's Court
1 Tennis Street
London
SE1 1YD

Medicines and Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

+44 (0) 20 3080 6000

gov.uk/mhra

Date 15th April 2021

Dear Dr Harris

Regulation 28 Report concerning Ruben Bousquet; [redacted]

Thank you for your letter of 18th December 2020 in which you asked the Rt. Hon Matt Hancock, Secretary of State for Health and Social Care, to provide a response to a Regulation 28 Report to Prevent Future Deaths following the inquest into the tragic death of Master Ruben Bousquet.

Your report raised a matter of concern regarding the availability of emergency Adrenaline Auto-injector devices (AAIs) in the Retail food sector. You recorded that the court heard no substantive evidence on whether this matter has been officially investigated. You further requested that consideration should be given to the feasibility of wider access to AAIs.

The Medicines and Healthcare products Regulatory Agency (MHRA), an executive agency of the Department of Health and Social Care (DHSC), is responsible for the regulation of medicines in the UK. In 2019 and 2020 MHRA sought advice from the UK Commission on Human Medicines (CHM), its independent scientific advisory committee, on a range of areas to support the effective and safe use of AAIs. Members of the CHM include a range of clinical and technical experts and lay representatives. CHM advice was sought after coroners' inquests into fatalities from anaphylaxis highlighted a range of issues in relation to the prescribing and use of AAIs. The feasibility of making AAIs available in the wider community, as a means of providing emergency treatment for anaphylaxis in exceptional circumstances, was also raised.

Although potential risks in making AAIs more widely available were noted by the CHM, the potential for life-saving benefit was clearly acknowledged provided the risks could be managed. Risks which were highlighted by the CHM include the difficulty of distinguishing collapse due to anaphylaxis from collapse due to other causes where the administration of adrenaline might be harmful as in some types of cardiac or cerebrovascular event (heart attack or stroke). Challenges also lie in correct and secure storage of AAIs to ensure that the adrenaline does not deteriorate and the device remains functional, also, the need for use by a person trained in the recognition of anaphylaxis and the correct administration of AAIs. Notwithstanding these challenges, the CHM recognised the vital lifesaving benefit that wider availability of AAIs could bring and concluded this should be examined in more detail.

In March 2020 the CHM agreed to the formation, and Terms of Reference, of an Adrenaline Auto-injector Expert Working Group (AAI EWG) to examine a range of cross-cutting areas to support the

effective and safe use of AAIs for the emergency treatment of anaphylaxis, including wider availability. The AAI EWG met on a number of occasions between April and July 2020 during which a number of areas were examined and a series of recommendations were made. In July 2020 CHM endorsed the conclusions and recommendations of the AAI EWG and made some additional recommendations.

Following their review, the AAI EWG recommended *in principle* that AAIs should be made available in public locations for use to treat anaphylaxis in unforeseen, critical circumstances, provided suitable safeguards can be implemented to ensure effective and safe use of the AAIs. Cinemas offering food for sale, and other retail food outlets, were identified by the AAI EWG as examples of key locations where emergency AAIs could be envisaged to have particular potential to save lives. This could for example be individuals presenting for the first time with food-related anaphylaxis, or those who, through error or lack of awareness, may not be carrying their personally prescribed AAIs on their person, against advice.

Legislative amendment to the Human Medicines Regulation will be needed to effect such a key change in policy to make a prescription only medicine available for use in the community in an emergency on an unnamed basis. To safely implement the change, a requirement for training to ensure responsible acquisition and deployment of AAIs in a range of settings is envisaged. There are other significant considerations and prior to any such amendment, consultation with relevant stakeholders will be necessary to inform the feasibility and a hierarchy of need given the potential impact on AAI supply if a large number of outlets were to be involved.

Alongside the recommendations on wider availability, the AAI EWG recommended a number of other measures including reinforcement of the need for all patients at risk of anaphylaxis to carry two AAIs at all times; the need for administration of an AAI at the first signs of anaphylaxis and how to recognise this; the need for patients experiencing anaphylaxis to remain lying down; and the need for patients to know how to use their particular AAI device.

A report summarising the conclusions and recommendations of the AAI EWG, endorsed by the CHM, will be published by the end of May 2021.

The MHRA hopes that this initiative will provide you and the Court with reassurance that the matter has been, and is continuing to be, officially investigated and that the MHRA views this as a matter of significant public health importance. The MHRA will continue to advance progress towards an effective and safe, legally implemented, mechanism of widening access to AAIs in order to save lives in the future. This will also need to ensure that the future supply of AAIs will be able to meet the additional demand for AAIs that wider roll-out would bring, without compromising the supply of prescribed AAIs that remain the mainstay for protecting individuals at risk.

We will keep you informed of progress.

Yours sincerely

Chief Executive Officer
Medicines and Healthcare products Regulatory Agency