Arnold & Porter

[redacted]

FAO Ms Mary Hassell
Senior Coroner
Inner North London
St Pancras Coroner's Court
Camley Street
London N1C 4PP

16 March 2020

Our Ref:
Your Ref:

Dear Madam:

Regulation 28:Prevention of Future Deaths Report, Shanté Andreé Marie Turay-Thomas

This letter is sent on behalf of Bausch & Lomb UK Ltd (Bausch) in response to your report dated 27 January 2020 under paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and regulations 28 and 29 of the Coroners (Investigations) Regulations 2013.

You raise four matters of concern in relation to Bausch's product, Emerade at paragraphs 3, 4, 12 and 13 of your report. We respond to these below.

Review of advice to patients that two pens should be carried at all times

Paragraph 3 of your report states:

> "*The Emerade AAI accompanying leaflet does include the advice that two pens should be carried at all times, but the advice is not re-iterated on the outside of the box. Consideration will need to be given to whether this is the appropriate advice in all cases, but it seems worthwhile to review the issue as a whole.*
>
> *(I assume the same is true of the EpiPen and the JEXT, but I heard no evidence about these at inquest.)*"

Bausch believes, consistent with advice issued by MHRA[1], that the available evidence supports a recommendation that patients who are at risk of anaphylaxis should carry two adrenaline auto-injectors at all times and this is stated in the Patient Information Leaflet for Emerade. In contrast however, guidance issued by the British Society for Allergy and Clinical Immunology ("BSACI") states:

> "*There is no good evidence that issuing two AAIs is necessary or cost-effective **in most cases**. After an episode in A&E, awaiting proper risk assessment, the normal practice would be to issue one device*" [2].

Bausch supports a review of the recommendations issued by expert bodies to consider whether a consistent approach is possible in the interests of patients.

With respect to information on the labelling of medicinal products, this is controlled by the Human Medicines Regulations 2012 and the addition of any text must be approved by the competent regulatory authority before it can be implemented. When considering the addition of information not specified in the regulations, it is necessary to take into account whether this can be included on the packaging in legible form without adversely impacting the essential information already required to be present.

Despite the current inconsistency of views held by MHRA and the BSACI, Bausch will initiate discussions with MHRA in relation to whether it would be appropriate to add advice regarding the need to carry two pens, similar to that included in the Patient Information Leaflet for Emerade, on the outer packaging of adrenaline auto-injectors.

Emerade supplied singly or in twin-packs

Paragraph 4 of your report states:

> *"The Emerade AAI is sold singly. It could be sold in boxes of two as the norm and only singly in the alternative."*

Emerade, like other adrenaline auto-injectors is authorised for supply as twin-packs as well as single auto-injectors.

There are a range of circumstances in which a single pen, rather than a twin-pack, may properly be prescribed and dispensed for a particular patient including:

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1 https://www.gov.uk/drug-safety-update/adrenaline-auto-injectors-updated-advice-after-european-review

2 Ewan P et al. BASCI Guideline: Prescribing an Adrenaline Auto-injector. Clinical and Experimental Allergy 2016; 46(10): 1258

- Where the patient needs to replace only a single pen which has been lost, damaged, used or has reached the end of its shelf-life; and

- Where the patient wishes to keep a further pen at, say, school (in addition to the pens carried with him/her).

Furthermore, while guidance consistently recommends the prescription of at least two adrenaline autoinjectors for patients with multiple risk factors for severe anaphylaxis, the position for other patients is less clear.

In circumstances where there will always be a need for single adrenaline auto-injectors to be dispensed in some situations and where the number of auto-injectors supplied depends on the prescription and not the pack size, Bausch & Lomb suggests that, even if packs of two auto-injectors are available, there will continue to be a parallel requirement for routine supply of packs containing a single auto-injector .

Finally, supply of a twin-pack containing two auto-injectors may not prevent patients who should carry two auto-injectors, dividing the pack and keeping the pens in separate locations. Supply of a twin-pack cannot therefore replace the need for patient education in relation to the number of pens to be carried at all times.

Reference to training by a healthcare professional in the patient information leaflet

Paragraph 12 of your report states:

> *"The Emerade AAI (and I assume the EpiPen and JEXT) leaflet does not specifically advise that training from a healthcare professional is needed in how to use this particular AAI as opposed to any other".*

However, the wording of the Patient Information Leaflet for Emerade includes the following information, specifically advising patients that training from a doctor or pharmacist is required:

> "*Always use Emerade exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure*".

This reflects the information in the Summary of Product Characteristics, which is the "datasheet" provided for healthcare professionals:

> "*All patients who are prescribed Emerade should be thoroughly instructed to understand the indications for the use and the correct method of administration*

*(see section 6.6 [*Which provides detailed instructions on administration*]). It is strongly advised also to educate the patient's immediate associates (e.g. parents, caregivers, teachers) for the correct usage of Emerade in case support is needed in the emergency situation*".

The use of trainer pens

Paragraph 13 of your report states:

> "*I heard that the gold standard of training for use of any AAI is to give the patient the relevant pen (whichever that patient is prescribed) containing a placebo rather than adrenaline and, following appropriate instruction, ask the patient actually to administer a dose.*
>
> *I heard at inquest that the incidence of this standard of training (in any setting) is rare. That may be for good reasons, but it seems that revisiting best practice training at a national level would be helpful*".

Bausch distributes trainer pens to allergy clinics and further supplies may be accessed through the Emerade website by all patients for practice purposes. These trainer pens do not include a placebo as this would limit use of the trainer pen to single use and, by administering an apparent "dose", would present a risk of confusion, with implications for patient safety.

Bausch is currently reviewing the design of its trainer pens and plans to incorporate a needle cover shield extension when activated, to more closely replicate the patient experience with the actual pen, albeit still capable of being used on multiple occasions for practice purposes.

We trust that this letter addresses the concerns raised in your report in relation to adrenaline auto-injectors in general and Emerade in particular. Please contact us should you require any further information.

Yours faithfully,

Arnold + Porter Kaye Scholer

Arnold & Porter Kaye Scholer (UK) LLP