Department of Health

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From the Rt Hon the Earl Howe P.C.
Parliamentary Under Secretary of State for Quality (Lords)

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Mr M Fleming
Assistant Coroner,
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8 August 2014

Dear Mr. Fleming,

Thank you for your letter following the inquest into the death of Archie Hames. In your report you conclude that the cause of death was cerebral hypoxia, airway obstruction (dislodged tracheal tube) and CHARGE syndrome. I was sorry to read of the events that led to Archie Hames' death and wish to extend my sincere sympathies to his family.

You raise the following matters of concern:

- Independent expert testing of the tracheostomy tube (Arcadia Medical) and attaching Velcro strap (Kapitex Healthcare) confirmed that their combined use compromised the integrity of the silicone eyelet to the tracheostomy tube and was more *likely* than not to have caused the detachment of Archie's tube;
- The further implications of such continued use; and,
- The implications of using Velcro strap attachments with other tracheostomy tubes.

and ask that we consider:

- the appropriateness of using Velcro strap attachments with tracheostomy tubes.

We have taken advice and comment from NHS England and the Medicines, Healthcare and Regulatory Agency (MHRA).

Officials at NHS England have been assured by MHRA that the type of flange damaged by Velcro in this case is no longer on the market. They have also undertaken a review of incident data reported to the National Reporting and Learning System (NRLS), to find any evidence where

Velcro has damaged the flange of other like devices. Despite there being no evidence of any similar incidents, NHS England understands and accepts the advice from the testing laboratory that in laboratory conditions, it is slightly easier to break the flange with Velcro than with tapes.

In addition, there are other causes and circumstances that lead to dislodgement of tracheostomy tubes as evidenced in NRLS data and in a recent report from the National Confidential Enquiry into Patient Outcome and Death (NCEPOD).

NHS England has considered whether it is safe and realistic to ban the use of Velcro to secure tracheostomies. A wider review of NRLS data and clinical practice suggests there are risks as well as benefits in using either fastening system, and that a ban on Velcro might introduce new unintended risks. It might also not be considered acceptable by some patients and carers.

NHS England therefore propose initiating discussions with partner agencies including NCEPOD and Patient Safety Expert Groups (PSEGs) to agree how all parties can take forward wider quality improvements to reduce the risk of tracheostomy dislodgment, including, but not limited to, the best methods of securing these devices. We would be happy to keep you updated with progress as this work goes forward.

MHRA were originally made aware of the death of Archie Hames in 2012, and coordinated an investigation with the hospital and manufacturers of the involved medical devices which resulted in a report detailing their conclusions and outcomes. Further detail about this report is included in the MHRA's full response to your Regulation 28 letter, which is provided at **Annex A.**

MHRA will continue to survey and monitor any incidents with these products and ensure that instructions for their use result in safe use.

I hope that this response is helpful and I am grateful to you for bringing the circumstances of Archie Hames's death to my attention.

Yours sincerely,

[redacted]

EARL HOWE

ANNEX A

MHRA Response to Regulation 28 Report from Martin Fleming Assistant Coroner for Surrey

The MHRA was made aware of the death of Archie Hames on 18th January 2012 by Guys and St Thomas Foundation Trust. The MHRA coordinated an investigation with the hospital and manufacturers of the involved medical devices and produced a report for the coroner on 16th May 2012 under the reference MHRA Ref. 2012/001/018/401/003.

MHRA's investigation identified:

- Tracheostomy tubes and their integrated flanges can be made from various materials for example PVC, silicone or silver and they are supplied, by tracheostomy tube manufacturers, with compatible attaching material e.g. twill tape
- The Arcadia Medical tracheostomy tube, in the Archie Hames case, was supplied with twill tape. A local healthcare professional decision was made not to use the twill tape supplied, but rather a Velcro holder supplied by Kapitex.
- Arcadia Medical investigation showed that the Velcro holder had damaged the eyelets on the tracheostomy tube's silicone flange allowing the tube to become free from the holder and dislodge.
- The tracheostomy tube's instructions for use, at the time of the incident advised to avoid contact with sharp edges, inspect condition of device at every use and cleaning, and use the twill tape supplied with the tube and tie through the flanges to secure the tube to the patient's neck.
- The tracheostomy tube had been in use for 31 days which is 2 days longer than recommended by Arcadia Medical.

MHRA investigation outcomes:

- MHRA's incident database showed that Arcadia Medical and another manufacturer, Smiths Medical, had filed reports of damage to their tracheostomy tube's silicone flange by a Velcro holder.
- Arcadia Medical and Smiths Medical agreed to clarify their instructions for use to include a specific warning not to use Velcro holders with their silicone flange tracheostomy tubes.
    - Arcadia Medical issued a Field Safety Notice (see attachment) to all their customers on the 7th June 2012 informing them that the instructions for use for their silicone tracheotomy tubes had been enhanced and now included the

warning to not use Velcro. In 2012 Arcadia Medical developed a nylon insert to reinforce the silicone flange eyelet. From December 2012 Arcadia Medical appear to have ceased trading and no longer sell tracheostomy tubes.

  - Smiths Medical clarified the instructions for use of their Bivona silicone tracheostomy tube to include a specific warning against use of Velcro holders in July 2013. In May 2013, prior to the instructions being changed, brightly coloured warning inserts were placed with devices to inform healthcare professionals about changes to the instructions for use.

- MHRA also liaised with the manufacturer of the Velcro holder, Kapitex. On 17 March 2012 Kapitex removed the claim from their web-based product literature, that their Trachi-Hold and Velcro holder were "suitable for all brands of tube".
- The MHRA issued a Generic Medical Device Alert (MDA/2012/062) on 11th September 2012 to all UK Hospitals highlighting the risks and changes to instructions for use for some silicone tracheostomy tubes. A copy of MDA/2012/062 is attached.

MHRA post-investigation incident surveillance:

- Between May 16th 2012 and July 2nd 2014, the MHRA received 7 reports of damage to the silicone flange of the tracheostomy tube which were confirmed to be the result of use of a third party Velcro holder. The last of these reports was in April 2013.
- MHRA continues to monitor the situation and ensure instructions for use have clear warnings regarding the safe use of the products.