ANNEX A

REGULATION 28: REPORT TO PREVENT FUTURE DEATHS (1)

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** 1. **Mr Jeremy Hunt MP, Secretary of State for Health , Department of Health, Richmond House 79 Whitehall London SW1A 2NS** 2. **Dr Ian Hudson, Chief Executive, Medicines and Healthcare Products Regulatory Agency(I would request separate responses from the medicines and Medical Devices Division)151 Buckingham Palace Road London SW1W 9SZ** 3. [redacted] **Director Of Patient Safety, NHS Improvement, 133-155 Waterloo Road London SE1 8UG** 4. **Chief Executive of the Proprietary Association of Great Britain, Vernon House Sicilian Avenue London WC1A 2QS** 5. **Chief Executive, Thornton and Ross Ltd ,manufacturers of Zerobase emollient cream, Manchester Road, Linthwaite, Huddersfield, West Yorkshire HD7 5QH** 6. **Chief Executive, LOCALA , Beckside Court First Floor, Bradford Road Batley WF17 5PW** 7. **Chief Executive, U.K Home Care Association, Sutton Business Centre Restmor Way Wallington Surrey SM6 7AH** 8. **Chief Executive, Care Quality Commission, 151 Buckingham Palace Road London SW1W 9SZ** 9. [redacted] **Systems Compliance Manager Arjo Huntliegh, (manufacturers Nimbus 6 of airflow mattress)Houghton Hall Business Park, Houghton Regis, Bedfordshire LU5 5XF**
	CORONER I am Mary Burke Assistant Coroner, for the coroner area of West Yorkshire Western District.
2	**CORONER'S LEGAL POWERS** I make this report under paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and regulations 28 and 29 of the Coroners (Investigations) Regulations 2013.
3	**INVESTIGATION and INQUEST** On the 9th June 2015 an inquest was opened into the death of Pauline Taylor, aged 74 years. The inquest concluded on 28th April 2017. The conclusion of the inquest was accidental death. The medical cause of Mrs Taylor death was due to smoke inhalation and burns.
4	**CIRCUMSTANCES OF THE DEATH** Mrs Taylor lived alone at 108 Whitehead Lane Huddersfield, a 2 bedroom ground floor flat. She was becoming increasingly immobile due to a number of significant health issues and from March 2015 she had become bedbound.

She had a longstanding history of psoriasis and was treated with daily applications of Zerobase emollient cream.

Mrs Taylor was a regular smoker and smoked in bed despite being repeatedly advised of the fire hazards by health care professionals and various members of her family.

Mrs Taylor was of sound mind and had full mental capacity.

Mrs Taylor was supported in her home by numerous daily visits by both carers provided by Care Watch Services, District Nurses provided by Locala and a very supportive family.

Mrs Taylor was provided with a medical bed with a Nimbus 6 dynamic airflow mattress in place manufactured by Arjo Huntleigh,

The property had a fire alarm system fitted which was connected to a care alert facility which in turn was linked to a monitoring unit provided by the local authority which was manned 24 hours a day.

On the 29th May 2015 upon the request of Mrs Taylor one of her carers purchased a box of matches for her, as her safety lighter was no longer working.

She was last visited by Locala team of carers at 23.30 hours on the 29th May 2015 when Mrs Taylor was alert and her presentation gave no cause for concern.

Just after 4.10 hours 30th May 2015 an operator in the monitoring unit identified that the smoke detector in the hallway of Mrs Taylor's home had been activated.

Fire officers from West Yorkshire Fire and Rescue Services were despatched and subsequently attended Mrs Taylor home, sadly she was found by officers to have died laid on her bed.

There was evidence that there had been a rapidly developing fire that was now in its decay stage, which had been localised in and around Mrs Taylor's bed.

Initial investigations undertaken by West Yorkshire Fire and Rescue Services concluded that the cause of the fire was due to a match or cigarette coming into contact with non fire retardant bedding.

It was also considered likely that magazines and matches which were on Mrs Taylor's bed had contributed to the speed and intensity of the fire.

Subsequently West Yorkshire Fire and Rescue Services undertook a number of controlled fire tests using various types of mattresses including a Nimbus 6 airflow mattress and night clothes and bedding similar to those which Mrs Taylor had on her bed, in some of the tests Zerobase emollient cream was impregnated upon the bedding and nightclothes.

The results revealed that the presence of Zerobase emollient cream caused the fires to develop with much greater speed and intensity as compared to those tests where no Zerobase emollient cream was present.

In addition the tests also revealed that the polyurethane material used in coating the outer surface of the airflow mattress is likely to have intensified the fire causing the mattress to burn hotter and more quickly.

West Yorkshire Fire and Rescue Service gave evidence at the inquest that in light of the results of these controlled test results they concluded that the airflow mattress and the presence of Zerobase emollient cream in Mrs Taylor's case is likely to have contributed to the speed and intensity of the fire that occurred on the 30th May 2015 at her home.

Evidence presented at the inquest suggested that various previous alerts and guidance had been issued to the medical profession, advising that emollient creams posed a fire risk, however the alerts appeared to indicate that such a risk related only to emollient creams which had a much higher paraffin content to the levels contained in other forms of emollient creams such as Zerobase.

The Managing Director of Care Watch Services(one of the major community care providers in the country), the company who employed some of Mrs Taylor's carers indicated in evidence that companies which provide private community care do not receive regular alerts concerning medicines drugs or devices.

I have sought approval from West Yorkshire Fire and Rescue Service that I may disclose their report of the subsequent controlled fire tests using various mattresses and Zerobase emollient cream. If any recipient of my report wishes to have sight of this report please contact [redacted] her email address is [redacted]

5 **CORONER'S CONCERNS**

During the course of the inquest the evidence revealed matters giving rise to concern. In my opinion there is a risk that future deaths will occur unless action is taken. In the circumstances it is my statutory duty to report to you.

The **MATTERS OF CONCERN** are as follows. –

[BRIEF SUMMARY OF MATTERS OF CONCERN]

(1) Zerobase and other emollient creams which contain a low level of paraffin pose a potential fire hazard risk.

(2) Warnings of such risks are not displayed on all product packaging.

(3) Health care professionals both in a hospital and community setting may not be aware of the potential fire hazard posed by emollient creams which contain a low level of paraffin.

I understand from subsequent enquiries I have made that a number of public bodies are presently undertaking a review of the risks posed by emollient creams in order to consider whether further advices/ alerts should be issued to the medical profession and further afield.

It is clear that this is a complex area as some of these products are registered as medicines and some as medical devices and therefore different regulatory provisions apply. Notwithstanding such differences I would ask that my concerns be considered by both the medicines and medical devices divisions of the appropriate regulatory bodies and that each division provide a separate response to this report.

(4) Members of the public are able to purchase emollient creams across the counter but are not verbally made aware of the potential fire hazards of emollient cream containing a low level of paraffin.

(5) Private companies who provide carers in the community do not receive alerts with regard to medicines and medical devices which could impact on the risk assessments and the manner in which carers working in the private sector provide care.

(6) Care homes (in both the local authority and private sector) who provide residential/nursing care may not be aware of the potential fire hazard risk of emollient creams which contain low levels of paraffin.

(7) The polyurethane coating used in the outer covering of the nimbus 6 airflow mattress appears to have contributed to the speed of the fires development and also its intensity.

(8) Following a significant change in Mrs Taylor's circumstances in March 2015 a further risk assessment had not been undertaken by Locala.

(9) A further fire risk assessment referral/review was not offered to Mrs Taylor by Locala following a major change in her circumstance (she had become bedbound in March 2017.)

6 **ACTION SHOULD BE TAKEN**

In my opinion action should be taken to prevent future deaths and I believe the recipients of this report have the power to take such action.

7	**YOUR RESPONSE** You are under a duty to respond to this report within 56 days of the date of this report, namely by 14th September 2017. I, the coroner, may extend the period. Your response must contain details of action taken or proposed to be taken, setting out the timetable for action. Otherwise you must explain why no action is proposed.
8	**COPIES and PUBLICATION** I have sent a copy of my report to the Chief Coroner and to the following Interested Persons [redacted] and [redacted], Mrs Taylor's daughters and DACbeachcroft Solicitors legal representatives for West Yorkshire Fire and Rescue Service I am also under a duty to send the Chief Coroner a copy of your response. The Chief Coroner may publish either or both in a complete or redacted or summary form. He may send a copy of this report to any person who he believes may find it useful or of interest. You may make representations to me, the coroner, at the time of your response, about the release or the publication of your response by the Chief Coroner.
9	**[DATE]** 21/7/2017 **[SIGNED BY CORONER]**