

**ANNEX A****REGULATION 28: REPORT TO PREVENT FUTURE DEATHS (1)**

	<p><b>REGULATION 28 REPORT TO PREVENT FUTURE DEATHS</b></p> <p>THIS REPORT IS BEING SENT TO:</p> <ol style="list-style-type: none"><li>1. Rt Hon Dr Vince Cable M.P</li><li>2. [REDACTED] – Director General CPTA</li><li>3. Chief Coroner - HH Judge Peter Thornton QC</li></ol>
1	<p><b>CORONER</b></p> <p>I am Geoffrey Fell, Assistant Coroner, for the coroner area of Western Area of North Yorkshire</p>
2	<p><b>CORONER'S LEGAL POWERS</b></p> <p>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.</p>
3	<p><b>INVESTIGATION and INQUEST</b></p> <p>On 30/11/2012 I commenced an investigation into the death of Julie McCabe (aged 39). The investigation concluded at the end of the 3 day, inquest on 19/02/2015</p> <p>The conclusion of the inquest was: -</p> <p><b>Accidental death due to a rare but known potential adverse reaction to hair dye which caused irreversible brain damage due to anaphylactic shock on 30th October, 2011.</b></p> <p>Cause of death was: -</p> <p><b>1a) Acute Cardiorespiratory Arrest</b> <b>1b) Longstanding Severe Anoxic Brain Damage</b> <b>1c) Anaphylactic Shock on 30th October 2011</b></p>
4	<p><b>CIRCUMSTANCES OF THE DEATH</b></p> <p>Julie McCabe died as a result of an adverse reaction to a chemical component contained in hair dye. That component; Para-Phenylenediamine (PPD) is a long recognised potent and powerful allergen. Julie and her treating G.P.'s were aware of her longstanding allergy to hair dye going back to at least 2005. Julie was known to have had a black (probably) henna tattoo in 2007. The frequency of her visits to the G.P. increased after 2007. <b>Black Henna, which contains PPD, is known to sensitise people who use hair dye which also contains PPD.</b> That is all permanent and to a lesser extent, some non-permanent hair dye</p> <p>Julie had used hair colourants for probably 10 years before she died. During that time she had visited her G.P.'s surgery 16 maybe 20 times, and the local hospital twice following adverse reactions. Evidence was given that Julie would have a reaction every time she used hair colourant. It would appear she did not seek professional help every time.</p>
5	<p><b><u>CORONER'S CONCERNS</u></b></p> <p>During the course of the inquest the evidence revealed matters giving rise to concern. In my opinion there is a risk, probably slight, that future deaths will occur unless action is taken. In these circumstances it is my statutory duty to report to you. The matters of concern are as follows: -</p>

**Background: -**

- PPD is used in all permanent hair colourants. It has long been known as a powerful allergen.
- It has been the subject of numerous research papers
- Since 1979 the effects of PPD have been considered by the Scientific Committee on Consumer Safety (SCCS) of the European Commission on 6 occasions, the last in 2012
- The 2012 report referred to in excess of 200 research documents.
- No other component of a cosmetic has been the subject of so much research as PPD
- The SCCS said in 2012 “ ...PPD in hair dye remains a considerable concern for consumer safety”
- Hair colourant used in the EC cannot legally contain more than 2% PPD which at the scalp equals 1mg (1/5 of a teaspoon of PPD).
- Anaphylaxis is a rare but documented reaction according to research within the industry.
- The SCCS in 2012 also noted that exposure to temporary tattoos (black henna) may also result in sensitisation in consumers.
- In addition to anaphylaxis a more common (but rare according to the industry) may be oedema of the face, eyelids and scalp.
- More moderate reaction such as erythema, suppuration and ulceration at the scalp margin, on the ears and sometimes with eczema where the dye has run down the neck are seen.
- About half of today's population have dyed their hair at some time or other, again according to industry research.

**Matters of Concern****A)**

- The hair colourant industry generally, rely almost entirely on 'reports' for information concerning adverse reaction to hair dye from users. So called, spontaneous reports.
- The industry accepts these reports are an efficient way of collecting information, but no more than that. They result in very small samples
- The industry statistics for such matters are calculated on 'reports per million sold'.
- From the industry's figures, best case is 0.3 per million, worst is 4.3 per million.
- There is a massive disconnect with some independent research.
- For example. Work carried out by Amersham hospital with a sample of 1800 revealed:
  - 14% (270) of users reported an allergic reaction of some nature,
  - 15% (36) of those sought medical help
  - And 0.02% reported their reaction to the manufacturers.
- Extrapolation of those figures to the industry standard per million:
  - 140,000/million have some allergic reaction to hair dye colourant;
  - 21,000 would seek medical help
  - 5 would report it to the manufacturer
- It was said in evidence that the true figure will lie somewhere between those two 'very' extremes.
- There is further independent research suggesting that perhaps as many as 50% of users have to a greater or lesser degree some reaction. A significant number of those at the 'lesser' end do continue to use hair dye..
- It was generally accepted in evidence that repeat users who continued to suffer a reaction and were willing and able to tolerate the effects, were unlikely to

## ANNEX A

### REGULATION 28: REPORT TO PREVENT FUTURE DEATHS (1)

report it to the manufacturer.

- It was also clear that the medical professionals are under no obligation, nor have they been asked, to report any adverse reaction to hair dye to anybody.
- The instruction provided with colourant advises a test 48 hours before using. Research indicates that only 5% carry out the test, even though 86% are aware of the necessity of the test.
- The instructions included in the hair dye kit, also advise users to seek medical assistance if they do have a reaction, including shortness of breath, to hair dye
- The instructions, in L'Oreal hair colourant do not advise those who suffer an allergic reaction of any kind to contact the manufacturer. Their trade association does advise that such information should be included in the instructions for use leaflet

**My concern is that the industry has no accurate information on the level of allergic reaction to PPD:**

- **Not its scale, nature or severity**
- **Nor do they actively seek that information**

**It was said in evidence that the level of the risk would dictate the warnings contained in the kit.**

**I would suggest, by analogy, it will also dictate the level of resources, their nature and how and where they are to be focussed to address the allergic problems associated with PPD.**

**Unfortunately for the relatively small but probably significant percentage, of the tens of millions of users who annually buy hair colourant, and who have a n allergic reaction, the industry does not have that level or detail of information. Until they have that information or come up with a safer alternative to PPD a small minority, (probably) of consumers will be at risk of anaphylaxis and the risks associated with that medical condition.**

**A much larger number of consumers will continue suffer the less life threatening consequences of an allergic reaction to PPD**

#### **B)**

My second concern is the effects of Black Henna, (as opposed to normal Henna) which will contain PPD probably well in excess of that permitted under the cosmetic regulations I am told that this substance is illegal throughout the E.C. when used for tattoos. The artisan tattooists who offer these tattoos are often found on beaches, fairgrounds and festivals. Research by the Spanish Authorities in the Canary Islands indicates a PPD content in Black Henna there of between 15% and 64%. The permitted level in henna tattoos in the EC is 2%.

It is likely that similar strength black henna is used elsewhere in the EC.

Black Henna will no doubt be available in the UK but the evidence suggested the major problem is in holiday resorts abroad. I was told that travel companies refuse to co-operate with the trade body: - Cosmetic, Perfume and Toiletries Associations (CPTA) of the cosmetic industry to include a warning notice in travel brochures about the possible consequences of temporary tattoos

I have alerted my local authority, North Yorkshire County Council Trading Standards Department to the issue of black henna tattoos. As the enforcing authority they have

said they will monitor what is happening in the county, particularly the larger holiday resorts on the east coast, come summer  
I'm hoping that approach will be communicated to other local authorities with the power to confiscate black henna that is being used for temporary tattoos

**My concern is that without adequate warnings children, in particular, could be offered one of these temporary tattoos. That first tattoo, particularly at the strengths being quoted can sensitise that person, adult or child, for life.**

**In the case of children the effects may not show themselves until much later in life. Perhaps flaring up on the first occasion they dye their hair, I am told that a black henna tattoo, like a hair colourant containing PPD, will not necessarily cause an allergic reaction on the first occasion it is used**

**C)**

n allergic reaction to the test required to be conducted 48 hours before using, are being required to buy a hair dyeing kit for some £8+The kit is then worthless. Once opened the contents have a limited life. The contents of the colourant sachet oxidise when exposed to air.

To expect a consumer to simply throw away £8 reflects the views of someone who is perhaps not living in the real world. It is not going to happen very often, not with a product that is all about a person who wants to feel good about themselves. In some cases consumers may also be motivated by vanity

It was said that PPD was cheap.

The test involves a small 'dab' behind the ear.

It was said by one expert that a free small tester phial which included PPD was an excellent idea.

Such a phial could be picked up at a retailer, perhaps the week before: was the thought that crossed my mind.

Unfortunately it was said that such a phial would have the effect of taking the sample containing PPD from being a cosmetic to a medicinal substance and subject to a different licensing regime.

**My concern is the industry is being a little naive in expecting consumers to simply throw away a beauty product which then, unfortunately turns out to be a £8 testing kit.**

**The statistics and some of the research papers referred to at the inquest quite clearly showed that a substantial number of users will continue to dye their hair in circumstances that others might find difficult to comprehend.**

**So an £8 "tester kit" is not going to be routinely thrown away by a consumer in the manner which the remains of a free tester kit would be. And importantly, an allergic reaction to a free tester might, And I put it no higher than that, persuade someone who does have an allergic reaction, not to dye their hair.**

**Alternatively they might be persuaded to purchase a non-permanent hair dye which may not include PPD.**

**6 ACTION SHOULD BE TAKEN**

In my opinion action should be taken to prevent future deaths and I believe you and your organisation have the power to take such action.

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7	<p><b>YOUR RESPONSE</b></p> <p>You are under a duty to respond to this report within 56 days of the date of this report, namely by <b>28<sup>th</sup> April 2015</b>. I, the Assistant Coroner, may extend the period.</p> <p>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.</p>
8	<p><b>COPIES and PUBLICATION</b></p> <p>I have sent a copy of my report to the Chief Coroner and to the following Interested Persons: -</p> <p><b>██████████ – Director General, Cosmetic Toiletry and Perfume Association</b></p> <p>I am also under a duty to send the Chief Coroner a copy of your response.</p> <p>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.</p>