# **Regulation 28: Prevention of Future Deaths report**

Seema Pravin HARIBHAI (died 18.12.21)

#### THIS REPORT IS BEING SENT TO:

 Medicines and Healthcare Products Regulatory Agency (MHRA)
 South Colonnade Canary Wharf London E14 4 PU

- 2. Ayurvedic Professionals Association c/o ZRS Accountants
  Building 3
  North London Business Park
  Oakleigh Road South
  New Southgate
  London N11 1GN
- 3. Department of Health and Social Care 39 Victoria Street London SW1H 0EU
- 4. The Enterprise Practice
  Belmont Health Centre
  516 Kenton Lane
  Belmont
  Harrow
  Middlesex HA3 7LT

#### 1 CORONER

I am: Coroner ME Hassell

Senior Coroner Inner North London

St Pancras Coroner's Court

Camley Street London N1C 4PP

## 2 | CORONER'S LEGAL POWERS

I make this report under the Coroners and Justice Act 2009, paragraph 7, Schedule 5, and The Coroners (Investigations) Regulations 2013, regulations 28 and 29.

#### 3 INVESTIGATION and INQUEST

On 30 December 2022, I commenced an investigation into the death of Seema Haribhai, aged 37 years. The investigation concluded at the end of the inquest earlier today.

I made a determination that Seema Haribhai died as a consequence of the administration of Ayurvedic medicines intended to treat psoriatic arthritis.

I recorded a medical cause of death of:

- 1a) sepsis
- 1b) recurrent intestinal ischaemia
- 2 idiosyncratic Ayurvedic drug induced liver injury (treated with transplant)

#### 4 | CIRCUMSTANCES OF THE DEATH

Seema Haribhai suffered with psoriatic arthritis that was becoming increasingly disabling. She was concerned at the potential effects of conventional medication and so consulted an Ayurvedic practitioner, who prescribed an array of herbal based remedies. She took these, developed liver failure as a consequence, and died some weeks later.

### 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.

#### Medicines and Healthcare Products Regulatory Agency (MHRA)

I am aware that one of the treating hepatologists from the Royal Free Hospital attempted to report this matter to the MHRA under the yellow card scheme, but was in some difficulty because he could not identify which drugs or drug combinations had been prescribed and had caused the liver injury.

However, I now have the statement of the treating Ayurvedic practitioner detailing the medicines prescribed, and so I attach this in the hope that it will assist you.

# **Ayurvedic Professionals Association**

The Ayurvedic practitioner who prescribed the medicines that killed Seema Haribhai told me that she had undertaken a five year degree and a one year post graduate training to enable her to practise Ayurvedic medicine.

However, when she first discovered that her patient had developed a yellow discolouration, whilst she recognised that the liver was probably responsible, she did not recognise that the cause might be her own prescription. She did not advise the only course of action with the potential to save Seema Haribhai's life: an immediate cessation of all the herbal remedies.

Even when she gave evidence in court, the Ayurvedic practitioner did not seem to canvass the possibility that the medicines she had prescribed could have caused harm. She had at one stage advised her patient to have a routine blood test, but she had not at any stage advised immediate attendance at a hospital emergency department.

It appears from the evidence I heard in court that Ayurvedic practitioners do not necessarily have the possible complications of Ayurvedic treatment as part of their routine frame of reference. All medicines can cause harm, even those that are herbal based.

### Department of Health

I heard evidence at inquest that Ayurvedic practitioners are not in any way regulated. Even those who are members of the Ayurvedic Professionals Association receive as little as two hours of continuing professional development training per annum.

The medicines prescribed by Ayurvedic practitioners are manufactured abroad. I did not hear evidence of any quality control.

#### The Enterprise Practice

Seema Haribhai made an appointment with her general practitioner, explaining that she had taken Ayurvedic medicines, and complaining of yellow skin and yellow eyes. The doctor she consulted asked to see a photo of her face and ordered a blood test.

However, the GP did not record the detail of the history, he did not record exactly when the yellow discolouration first appeared, and he did not record the absence of any other signs and symptoms. He did not ask for attendance at the surgery so that he could perform a physical examination. He did not advise immediate cessation of the Ayurvedic medicines.

The GP consultation was on 5 November, the blood test was conducted on 9 November, the results came back to the surgery on 10 and 11 November, and an appointment was booked for 15 November. Meanwhile, same day admission to hospital was arranged on 15 November solely because a nurse had noted the blood test result at a routine rheumatology appointment.

The blood test result was so abnormal that, even without examination, the consult rheumatologist saw no option but immediate admission.

#### 6 ACTION SHOULD BE TAKEN

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

#### 7 YOUR RESPONSE

You are each under a duty to respond to this report within 56 days of the date of this report, namely by 5 September 2022. 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 following.

- , husband of Seema Haribhai
- Ayurvedic practitioner
- general practitioner
- hepatologist, Royal Free Hospital
- , rheumatologist, Northwick Park Hospital
- Care Quality Commission for England
- NHS England & NHS Improvement
- Professor Chris Whitty, Chief Medical Officer for England
- HHJ Thomas Teague QC, the Chief Coroner of England & Wales

I am also under a duty to send a copy of your response to the Chief Coroner and all interested persons who in my opinion should receive it. I may also send a copy of your response to any other person who I believe may find it useful or of interest.

	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.	
9	DATE	SIGNED BY SENIOR CORONER
	07.07.22	ME Hassell