Medicines & Healthcare products
Regulatory Agency

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Coroner ME Hassell
Senior Coroner
Inner north London
St Pancras Coroner's Court
Camley Street
London N1C 4PP
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17 January 2023

Dear Coroner Hassell,

Regulation 28: Prevention of Future Deaths report Seema Pravin HARIBHAI

Thank you for your e-mail of 11th July 2022 regarding a Regulation 28 Report to Prevent Future Deaths following the inquest into the death of Seema Haribhai, I am sorry for the delay in responding. The report raised a matter of concern 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 not able to submit a report online, as they did not have any details for the herbal products taken by the patient.

The Medicines and Healthcare products Regulatory Agency (MHRA) is the executive agency of the Department of Health and Social Care (DHSC) with responsibility for the regulation of medicinal products and traditional herbal medicinal products that hold a traditional herbal registration (THR) in the UK.

In the UK, reports of adverse reactions suspected to be associated with the use of a medicine are submitted to the MHRA via the Yellow Card scheme. Reports can be submitted by healthcare professionals, patients or family or carers on behalf of patients. The Yellow Card scheme is voluntary and reports can be submitted when there is a suspicion that a medicinal product or combination of products has caused a side effect. Reports are used alongside other safety information and help the MHRA to monitor the safety of products and take action if safety issues are identified. In addition to the electronic form for completing a Yellow Card, concerns about medicinal products can be raised via our free helpline (0800 731 6789) or via customer services by email (mhracustomerservices@mhra.gov.uk) or telephone (0203 080 6000)

In order to complete a Yellow Card report, details of the specific product or products suspected to have caused the adverse reaction must be provided along with an identifiable patient and reporter in order for a case report to be assessed. Using the additional information provided in the statement from [redacted], the herbal practitioner, regarding the Ayurvedic products provided, a yellow card report has been created with the reference number [redacted]

There is no statutory definition of 'herbal practitioner' in the UK. Anyone - irrespective of qualifications or experience - can practice herbal medicine in the UK and, after making a diagnosis and forming a judgment about the treatment required, can prepare and supply herbal medicine to a member of the public following a one to one consultation. There are a number of voluntary registers of herbal practitioners which require that certain standards of practice and education are met, but membership of these registers is not a legal requirement.

The exemptions in the Human Medicines Regulations 2012 that apply are:

- Regulation 3 (6) of the Human Medicines Regulations 2012 provides an exemption from the need for a manufacturer's licence and a marketing authorisation for a herbal product that is made up and supplied by a herbal practitioner on the premises following a one to one consultation with a member of the public.
- Regulation 3 (9) of the Human Medicines Regulation 2012 states that the herbal medicinal product is not manufactured or assembled on a large scale or by an industrial process.
- Regulation 241 of the Human Medicines Regulations 2012 allows herbal practitioners to prepare certain herbal medicinal products themselves on their premises using a range of single or multiple herbal ingredients following a one to one consultation, providing certain additional requirements are met.

The herbal practitioner has provided details of the ingredients she suggested and refers to these as food supplements and herbs. It is not clear from the herbal practitioner's statement if the preparations were made up under the herbalist exemption or whether they were recommended to the patient and then purchased elsewhere or if in fact it was a combination of both i.e. recommended and the practitioner provided herbs.

There are restrictions on what substances can be used by herbal practitioners to prepare unlicensed herbal medicines. Schedule 20 of the Human Medicines Regulations lists substances which are restricted or prohibited for use in unlicensed herbal products prepared by practitioners. None of the ingredients included in the herbal practitioners statement are included on the list of restricted ingredients.

However, it is important to note that the products referred to in the herbal practitioners statement are not licensed by the MHRA and therefore we are not able to comment on the quality control of the products taken by Seema Haribhai or any medicinal claims that may have been made for these products.

The MHRA continually monitor safety and ensure that possible side effects which have been recognised to occur with use of a medicine or tradition herbal remedy are appropriately described in the authorised product information. Unfortunately, as none of the products listed as being suggested to Seema Haribhai are authorised by the MHRA, we cannot comment on

what information that may have been provided with these products regarding their safety or possible side effects.

There is published literature regarding a risk of hepatotoxicity associated with traditional Ayurvedic herbs[1],[2] and this information would be taken into account if any of these products were submitted for authorisation by the MHRA.

No changes are proposed to the Yellow Card scheme as it is essential to have information about the specific products involved in order to assess the specific safety concern. The healthcare professional involved in the patients care did not have details of the herbal products taken and therefore could not complete the online form for the Yellow Card scheme. However, their concern about the safety of the herbal products could have been raised with the MHRA through multiple other routes while further details of the products were sought from the herbal practitioner either by the original reporter or the MHRA, if the MHRA were provided with the herbal practitioner's details.

The exemptions in the Human Medicines Regulations 2012, allow herbal practitioners to produce and supply herbal medicines following a one to one consultation with the patient. The MHRA has no regulatory oversight over products provided under this exemption.

I hope this information is of assistance.

Yours sincerely,

[redacted]
Head of Neuropsychiatric disorders, Cognition and Mental Health
Safety and Surveillance
[redacted]
[redacted]

[1] Comprehensive review of hepatotoxicity associated with traditional Indian Ayurvedic herbs - PMC (nih.gov)
[2] Case series and review of Ayurvedic medication induced liver injury | BMC Complementary Medicine and Therapies | Full Text (biomedcentral.com)