Secretary

Department of Health and Human Services

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Josh Munro
Coroners Registrar
Coroners Court of Victoria
65 Kavanagh Street
SOUTHBANK VIC 3006

Dear Mr Munro

Re: Coronial investigation into the death of Ronak Warty – COR 2013 005866

Thank you for your letter providing me with a copy of Coroner Jamieson's findings without inquest including recommendations into the death of Ronak Warty.

The Department of Health and Human Services (the department) has reviewed the following recommendations and provides a response to each at **Attachment 1**.

The department notes the seriousness of this tragic death and the desire to have a systematic approach to identifying and acting in a timely way to such causes of anaphylaxis.

Consistent with the Minister for Health's correspondence on 15 November 2016, I can confirm that the department will pursue a mandatory reporting scheme as part of the Duckett legislative reforms.

Should your office require further information in the interim, please contact Glenda Gorrie, Assistant Director, Quality and Safety on glenda.gorrie@dhhs.vic.gov.au or telephone (03) 9096 7553; or Fiona Jones, Manager Regulation and Incident Management, Food Safety Unit on fiona.jones@dhhs.vic.gov.au or telephone (03) 9096 5098.

Thank you for bringing this matter to the attention of the department.

Yours sincerely

Kym Peake
Secretary

12/ 12/ 2016

VICTORIA State Government

Attachment 1

Recommendation 1:

With the aim of protecting and promoting health in children with allergies and anaphylaxis, and monitoring, reporting and responding to circumstances that give rise to severe reactions in a timely and effective manner, I recommend that the Secretary of the Victorian Department of Health and Human Services, Ms Kym Peake, investigate, consult widely and formulate a program for mandatory reporting for children who present at hospitals and emergency departments with anaphylaxis.

Recommendation 2:

With the aim of more agilely and reliably responding to incidents triggering severe allergic or anaphylactic reactions, I further recommend that the Secretary of the Victorian Department of Health and Human Services, Ms Kym Peake, incorporate into the process of formulating the mandatory reporting program, interrogation of the sources of anaphylaxis, whereby if, as in Ronak's case, it becomes apparent that a contributing factor involves a packaged foodstuff, or labelling of a packaged foodstuff, the report can be directly referred to the department's Food Safety Unit.

Response to recommendations 1 and 2:

Safer Care Victoria is a new body recently established by the Victorian Minister for Health the Hon Jill Hennessey MP to monitor and improve the quality and safety of care delivered across the Victorian health system with the aim of achieving zero avoidable harm. Safer Care Victoria will scope the merits and practicalities of a reporting system such as that recommended above, and this will be informed by monitoring the department's response to Coroner Jamieson's third recommendation as described below.

As noted in Coroner Jamieson' s findings, the presence of food allergens in packaged foods is required to be declared on the product label under the Australia New Zealand Food Standards Code. Whilst there are no mandatory requirements for members of the public or health services providers, such as hospitals, to notify the relevant food regulator of cases of food-related anaphylaxis and/or potential food allergen labelling breaches, such matters can be reported for the necessary follow-up. The response to such notifications would typically include product testing by the food regulator and, where required, the overseeing of a food recall to ensure products are removed from the marketplace.

As also noted in Coroner Jamieson's findings, there is a separate mandatory reporting system in place in Australia under Australian consumer law, overseen by the Australian Competition and Consumer Commission. This mandatory reporting system stipulates that a food business must report to the Australian Competition and Consumer Commission the death, serious injury or illness of a person that the food business becomes aware of and was caused by the use of a consumer good, including food. It would appear in this tragic circumstance, that none of these pathways were activated.

Whilst the department is able to monitor anaphylaxis due to adverse food reaction generally, using current data captured in the Victorian Admitted Episodes Dataset, it is not, as noted in

Coroner Jamieson's findings, able to capture the situation of anaphylaxis due to incorrect food labelling. Further, the current reporting data set would not provide a timely identification or reporting system. Incident reporting systems would also be ineffective as they are unable to capture events which occurred outside of hospital care.

Anaphylaxis is a severe allergic response to an allergen, and comprises a range of symptoms, from hives, facial swelling, wheezing and coughing to acute and life-threatening effects including breathing difficulties which can result in death. The department's Paediatric Clinical Network is currently working with expert stakeholders to develop and promulgate a clinical practice guideline for health service response to acute anaphylaxis.

With respect to the Coroner's recommendations, the department will develop a legislative framework for a new mandatory reporting system in hospitals and emergency departments. As part of this process, anaphylactic reactions to incorrectly (illegally) labelled food would be notified to the department's Food Safety Unit.

In addition, the approach proposed below aims to strengthen and promote the use of notifications to the Food Safety Unit directly from members of the public and health service providers, whilst maximising the enforcement of already existing food allergen labelling laws, which the importer in this incident failed to comply with. This approach aligns with Coroner Jamieson's third recommendation, and is set out below:

Recommendation 3:

With the aim of increasing awareness of the need to report mislabelled packaged food products, I recommend that the Secretary of the Victorian Department of Health and Human Services, Ms Kym Peake, encourages the Food Safety unit to action the identified ways to improve reporting to food regulators of food allergen-related incidents, and take steps to provide educative information to, and relationship-building with, members of the public presenting to the medical community due to an allergic reaction to a food, and their parents; and the medical community (incorporating general practitioners, emergency rooms and hospitals).

Response to Recommendation 3:

I can confirm that the department's Food Safety Unit is currently finalising the drafting of an information sheet for people and parents presenting to their doctor, or at a hospital, with a food-related allergic or anaphylactic reaction to packaged food. This is part of the strategy aiming to strengthen and promote the use of notifications to the Food Safety Unit directly from members of the public and health service providers, whilst maximising the enforcement of already existing food allergen labelling laws, which the importer in this incident failed to comply with.

The intention of this resource is to explain the existing food labelling laws as they pertain to the declaration of food allergens on packaged foods, and to encourage patients, parents and medical professionals, to contact the Food Safety Unit to ensure any necessary action, including a food recall, can be initiated and overseen promptly, to ensure unsafe food is removed from the marketplace.

As advised in the department's Coronial statement of 27 May 2016, the Food Safety Unit responds to food allergen complaints frequently, and has a robust response process for doing so, underpinned by national food regulation enforcement policy which stipulates that matters of public health and safety are a priority. Due to the very high health risk to allergic members of the community that food allergens pose, when food allergen complaints are received, the Food Safety Unit treats these as a matter of urgency.

The department's information sheet will be actively promoted and disseminated to hospitals and general practitioners, and hosted on the Food Safety Unit's website. Translations will also be developed in consultation with Allergy and Anaphylaxis Australia as a key stakeholder. This work is expected to be finalised and disseminated by 31 December 2016, and the Food Safety Unit will provide the Coroner with copies of the information sheet and associated educative cover letters as soon as it is completed.

The department proposes to monitor and evaluate the effectiveness of the dissemination and use of the information sheet, to ensure that both the public and health service providers are aware of, and are actively using, the current reporting pathways. This work will be incorporated into Safer Care Victoria's review as described above.