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16 June 2016

An open letter to:
Professor Chris Baggoley
Chief Medical Officer
Australian Government Department of Health

Professor Baggoley

RE: CHALLENGING MANDATED OVER-VACCINATION WITH THE SECOND DOSE OF LIVE MEASLES, MUMPS AND RUBELLA (MMR) VACCINE

In your role as the Australian Government's Chief Medical Officer and principal medical adviser to the Minister and the Department of Health, **I request you take urgent action to ensure parents are properly informed of the alternative option of serological/antibody titre testing to verify immunisation after the *first* dose of live measles, mumps and rubella (MMR) vaccine, rather than being forced into having their child probably *over-vaccinated* with an arbitrary *second* dose of this live vaccine product.**

I suggest not informing parents of the alternative option of serological/antibody titre testing after the first dose of MMR vaccine contravenes the obligation for 'valid consent' before vaccination, as outlined in *The Australian Immunisation Handbook* (see below).

Background:

According to GlaxoSmithKline's data for the Priorix MMR vaccine, **most seronegative individuals are likely to be immune after the first dose of live GSK Priorix MMR vaccine (98.4% for measles, 94.8% for mumps and 100% for rubella)**¹, it appears a second dose is given to cover the small amount of individuals who might not have responded to the first dose. As two doses are stipulated on the National Immunisation Program Schedule², **this means the majority of individuals are *over-vaccinated with the second dose of live MMR vaccine***, if the vaccine is as effective after the first dose as claimed by the manufacturer, i.e. GlaxoSmithKline.

Professor Baggoley, in a letter dated 11 March 2016, Dr Masha Somi, Assistant Secretary of the Immunisation Branch, Office of Health Protection, advised me that the Commonwealth Chief Medical Officer, (i.e. you), had written ***"to all vaccination providers in December 2015 with advice about what vaccines are linked to family payments and the vaccines that are clinically recommended..."***

This information is outlined in the document **No Jab, No Pay – New Immunisation Requirements for Family Assistance Payments**, November 2015.

This document notes *two doses* of live measles, mumps and rubella (MMR) vaccine are 'required' (i.e. compulsory) for children to access tax and childcare benefits.

This document also states ***"Children with...natural immunity for certain diseases will continue to be exempt from the requirements"***, however the document also explicitly states: ***"Testing of children to assess serological status prior to vaccination is generally not recommended"*** and ***"If serology testing is undertaken, this is undertaken at the expense of the individual."***

Professor Baggoley, how can parents decide if they want to pay for serological testing if it is not made clear that this is an alternative option? *On what authority do you deny parents this alternative option?*

It appears likely most parents are not informed of the alternative option to have serological testing (also known as antibody titre testing) to verify immunity after the first dose of live MMR vaccine. Instead an arbitrary second dose of live MMR vaccine has been mandated by the Australian Government for children, which in most cases will provide no benefit to the already immune individual and may cause harm.³

I argue that parents should be informed of the alternative option of serological/antibody titre testing to verify immunity after the first dose of MMR vaccine, rather than be forced into having an arbitrary revaccination with a second dose of live MMR vaccine for their child. A positive blood test would provide evidence their child is immune, i.e. evidence-based medicine.

I suggest to not offer the alternative option of serological/antibody titre testing before the arbitrary second dose of live MMR vaccine contravenes the obligation for 'valid consent' before vaccination, as outlined in Section 2.1.3 of *The Australian Immunisation Handbook*.⁴ *The Australian Immunisation Handbook* acknowledges:

"In general, a parent or legal guardian of a child has the authority to consent to vaccination of that child..." and states "For consent to be legally valid, the following elements must be present:"

1. *It must be given by a person with legal capacity, and of sufficient intellectual capacity to understand the implications of being vaccinated.*
2. *It must be given voluntarily in the absence of undue pressure, coercion or manipulation.*
3. *It must cover the specific procedure that is to be performed.*
4. ***It can only be given after the potential risks and benefits of the relevant vaccine, risks of not having it and any alternative options have been explained to the individual.*** (My emphasis.)

Point 4 specifically states any 'alternative options' must be explained to the individual. I suggest in the case of the MMR second dose this is not happening in many cases, particularly for children, i.e. their parents are not being informed of the evidence-based option of serological/antibody titre testing to check if they are already immune after the first dose, **an option that some cautious/vaccine hesitant parents might be willing to pay for themselves.**

There is a precedent for parents being informed of the option of serological/antibody titre testing before their child being revaccinated with the second dose of live MMR vaccine.

In the state of New Jersey in the United States, the health department provides information on antibody titre testing. The Antibody Titer Law⁵ (Holly's Law) allows parents to seek testing to determine a child's immunity to measles, mumps and rubella *before* receiving the second dose of MMR vaccine.

The law was enacted in response to the death of five year old Holly Marie Stavola who died of encephalopathy which she developed seven days after receiving her second dose of MMR vaccine.⁶ Holly's family campaigned for this law, wishing they had known about the option of the antibody titre test before Holly's arbitrary revaccination with the second dose of live MMR vaccine.

Professor Baggoley, in your role as the Commonwealth Chief Medical Officer, I request you take urgent action to ensure parents are properly informed of the alternative option of serological/antibody titre testing to check if their child is already immune after the first dose of live MMR vaccine, rather than being forced into probable over-vaccination with a second MMR vaccine dose.

I request your early response on this matter.

Sincerely

Elizabeth Hart

<https://over-vaccination.net/>

cc: Dr Tony Hobbs, Principal Medical Adviser, Department of Health – Strategic Policy & Innovation
Professor Peter McIntyre, Director, National Centre for Immunisation Research & Surveillance
Professor Ross Andrews, Chair, Australian Technical Advisory Group on Immunisation
Professor Andrew Wilson, Chair, Pharmaceutical Benefits Advisory Committee

Attachment:

1. Antibody Titer Law – Information for Parents Brochure (New Jersey Department of Health and Senior Services)

References:

¹ According to the GSK Priorix Product Information Leaflet, in "a more recent study comparing the formulation of PRIORIX (albumin-free) with the previous formulation containing albumin, **antibodies against measles, mumps and rubella were detected in 98.4, 94.8 and 100% of previously seronegative subjects (n=191)**". The leaflet also contains similarly high seroconversion rates from earlier studies. The GSK Priorix Product Information Leaflet notes that: "**Seroconversion has been shown to equate with protection against each of the measles, mumps and rubella viruses.**" Despite the fact it appears **one dose** of PRIORIX MMR live vaccine is likely to provide protection for most previously seronegative subjects,

the GSK Priorix Product Information Leaflet indicates **two doses** are to be given, i.e. “*The Australian NH&MRC Immunisation Handbook recommendations for MMR vaccinations are as follows: MMR vaccine is recommended for all children at 12 months of age and again at 4-6 years of age unless there is a genuine contraindication.*” So it appears the NHMRC is behind the two dose ‘recommendation’. (Note: The second dose of live MMR vaccine is described as a ‘booster’ in the GSK Priorix Leaflet. I suggest the term ‘booster’ is misleading – what evidence is there to support an **already immune** individual needing a ‘booster’?)

² The National Immunisation Program Schedule (February 2016) stipulates that children have **two doses** of live measles, mumps and rubella (MMR) vaccine. The first dose of live MMR vaccine (GSK Priorix) is scheduled around 12 months of age. The second dose was previously scheduled for around four years of age, but this has now been changed to 18 months of age, with this second dose of live MMR vaccine being combined with varicella (chickenpox) vaccine, i.e. the MMRV (GSK Priorix-Tetra) which was introduced in July 2013.

³ Possible adverse effects after MMR vaccination are acknowledged in the *GSK Priorix Product Information Leaflet as accessed on the TGA website*. (Note: The second dose of live MMR vaccine is described as a ‘booster’ in the GSK Priorix Leaflet. I suggest the term ‘booster’ is misleading – what evidence is there to support an **already immune** individual needing a ‘booster’?)

⁴ Section 2.1.3 Valid consent. The Australian Immunisation Handbook, 10th Edition.

⁵ **Antibody Titer Law – Information for Parents.** (Holly’s Law) (NJSA 26:2N-8-11), passed on January 14, 2004, concerns vaccination of children with the Measles, Mumps, Rubella (MMR) vaccine. The law allows parents to seek testing to determine a child’s immunity to measles, mumps, and rubella, before receiving the second dose of the vaccine. This brochure has been prepared by the New Jersey Department of Health and Senior Services to assist parents in making the decisions related to the MMR vaccine and the test.

⁶ HopeFromHolly website. Providing NJ Physicians and Parents With More Knowledge about Childhood Vaccines.