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For the attention of: 19 March 2014

Professor Ian Olver
Chair, NMHRC Australian Health Ethics Committee (AHEC)

Professor Olver

RE: The Australian Government's requirement for revaccination of children with a second dose of live Measles/Mumps/Rubella (MMR) vaccine / lack of 'informed consent' / adverse events

The Australian Government's National Immunisation Program Schedule stipulates that children receive ***two doses*** of live measles/mumps/rubella (MMR) vaccines[1], and meeting this requirement is linked to obtaining Immunisation Related Payments for Parents.[2]

However, according to the GlaxoSmithKline PRIORIX Product Information leaflet, most seronegative children are likely to be immune after ***one dose*** of live MMR vaccine.[3]

I question whether parents are being given the opportunity to properly give their 'informed consent' to the ***second dose*** of the live MMR vaccine (or the MMR+varicella i.e. GlaxoSmithKline PRIORIX-TETRA MMRV vaccine) for their children. **This question is particularly pertinent as adverse events have been reported after MMR and MMRV vaccination.**

I request that the NHMRC Australian Health Ethics Committee respond to me on this matter, and I provide further supporting information below.

According to the 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.[4]

The PRIORIX Product Information Leaflet notes that: ***"Seroconversion has been shown to equate with protection against each of the measles, mumps and rubella viruses."***[5] The National Immunisation Program Schedule recommends the first MMR vaccination at 12 months of age[6], so presumably it is expected that most children will be seronegative at this age, i.e. maternally derived antibodies will have waned.

Despite the fact it appears ***one dose*** of PRIORIX MMR live vaccine is likely to provide protection for previously seronegative subjects, the PRIORIX Product Information Leaflet indicates ***two doses*** are to be given, i.e. ***"The Australian NH&MRC Immunisation Handbook recommendations for MMR vaccination 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."***[7]

It is notable that neither the PRIORIX[8] nor the PRIORIX-TETRA[9] Consumer Medicine Information leaflets contain information on the reportedly high seroconversion rates after live MMR vaccination. **Does this indicate that parents are not being informed of the reportedly high seroconversion rates after vaccination of previously seronegative children with the PRIORIX MMR vaccine product?**

It is also notable that there is no reference to the option of antibody titre testing to verify a response to MMR vaccination in either the Consumer Medicines Information leaflet or the Product Information leaflet for PRIORIX or PRIORIX-TETRA.

What are the ramifications here for 'informed consent'?

The Australian Immunisation Handbook provides criteria for consent to vaccination to be legally valid, i.e.:

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.*[10]

Professor Olver, I question whether parents are being properly informed by healthcare providers before administration of the second dose of measles, mumps and rubella vaccine, (whether via the MMR or MMRV injection).

In regards to point 2 above, I suggest parents are being ***pressured/coerced/manipulated*** to have the vaccine via the reward of Immunisation Related Payments. While the Immunise Australia website notes that *"benefits can be received without a child being fully immunised"*[11] this is only the case after completion of an *Immunisation exemption: Medical contraindication form*[12] or *Immunisation exemption: Conscientious objection form*[13]. I suggest that neither of these forms in their current format is appropriate in the case of the questionable second dose of the live MMR vaccine.

In regards to point 4 above, I question whether parents are being properly informed of the potential risks and benefits of the second dose of the MMR vaccine. **There are no benefits to the child if the child is already immune after the first dose.** There are risks, i.e. possible side effects, as detailed in the PRIORIX and PRIORIX-TETRA Consumer Medicine Information leaflets and Product Information leaflets. Are healthcare providers bringing this information to the attention of parents (and others)?

Reports of adverse events after MMR and MMRV vaccination have been submitted to the TGA's Database of Adverse Events.[14] (Refer to reports attached.) **For example a TGA list of adverse events after vaccination with PRIORIX, generated for the dates 1 January 2012 to 20 November 2013, indicates 674 adverse event reports were made in that period. 253 of these cases occurred in four year olds. Other age groups, (including adults), also reported adverse events after vaccination with PRIORIX. As it is likely many of these children had already been vaccinated with PRIORIX at 12 months of age and were likely already immune, (if the PRIORIX MMR vaccine is as effective as claimed), they underwent revaccination for no benefit.**

The MMRV vaccine was added to the Australian Government's National Immunisation Program Schedule in July 2013[15], for vaccination of children at 18 months of age, after vaccination with the MMR at 12 months of age. **A TGA adverse event list generated for the dates 1 July 2013 to 20 November 2013 shows 80 reports of adverse events after vaccination with the PRIORIX-TETRA MMRV vaccine product. If the children involved in these reports had already been vaccinated with the PRIORIX MMR vaccine at 12 months of age, again it is likely they were already immune to measles/mumps/rubella.**

It should be recognised that adverse events after vaccination are likely to be under-reported. The TGA acknowledges that reporting of adverse events to the TGA is voluntary, and that there is under-reporting in Australia, and around the world.[16] In regards to the lack of safety information for the MMR vaccine, the Cochrane Collaboration's systematic review of MMR vaccination notes: ***"The design and reporting of safety outcomes in MMR vaccine studies, both pre- and post-marketing, are largely inadequate."***[17]

Again in relation to point 4 above, **I also question whether "alternative options", e.g. antibody titre testing to verify a response to MMR vaccination, are being explained to parents by healthcare providers.** It is possible that some careful parents might prefer to pay for antibody titre testing, rather than have their child revaccinated with a probably unnecessary second dose of live MMR vaccine.

Parents of small children might be surprised to discover that vaccination 'best practice' for companion animals is now more advanced than that for children, with international vaccination guidelines for dogs re live vaccines recommending antibody titre testing rather than an arbitrary 'booster', i.e.: ***"…the principles of 'evidence-based veterinary medicine' would dictate that testing for antibody status (for either pups or adult dogs) is a better practice than simply administering a vaccine booster on the basis that this should be 'safe and cost less'".***[18]

Professor Olver, I question the ethics of coercing parents to have vaccinations of questionable benefit for their children. According to the vaccine manufacturer's data, it appears most seronegative individuals are likely to be immune after the *first* dose of MMR vaccine. It appears likely from TGA adverse event database information that children (and possibly adults) have suffered after revaccination with a *second* dose of MMR vaccine. I suggest there has been inadequate research undertaken on the possibly deleterious long-term effects of repeated vaccination, and so unnecessary vaccination should be avoided.

As the Australian Health Ethics Committee is responsible to advise the NHMRC on ethical issues relating to health, **I would appreciate your urgent response on this matter to my email address elizmhart@gmail.com**

Sincerely
Elizabeth Hart

***Please note this letter will be circulated to other parties.**

cc: Members of the NHMRC Australian Health Ethics Committee (AHEC)

- Dr Gary Allen
- Professor Vicki Anderson
- Professor Samar Aoun
- Professor Susan Dodds
- Associate Professor Ian Kerridge
- Dr Tammy Kimpton
- Rabbi Aviva Kipen
- Reverend Kevin McGovern
- Professor John McGrath AM
- Dr Eleanor Milligan
- Professor Robin Mortimer
- Ms Kay Oke
- Professor Margaret Otlowski
- Professor Debra Rickwood
- Professor Wendy Rogers
- Professor Loane Skene

and Professor Brian Martin, Social Sciences, University of Wollongong

References: (All links accessible as at 19 March 2014.)

[1] National Immunisation Program Schedule from 1 July 2013:
http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/nips-ctn
[2] Immunise Australia Program. Immunisation Related Payments for Parents. (Webpage dated 12 September 2013):
http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/related-payments
[3] GlaxoSmithKline PRIORIX Product Information:
https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2010-PI-05279-3
[4] *Ibid.*
[5] *Ibid.*
[6] National Immunisation Program Schedule from 1 July 2013:
http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/nips-ctn
[7] GlaxoSmithKline PRIORIX Product Information:
https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2010-PI-05279-3
[8] GlaxoSmithKline PRIORIX Consumer Medicine Information Leaflet:
https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2010-CMI-05278-3
[9] GlaxoSmithKline PRIORIX-TETRA Consumer Medicine Information Leaflet:
https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2013-CMI-01069-1
[10] 2.1.3 Valid Consent. 2.1 Pre-vaccination. The Australian Immunisation Handbook. 10th Edition 2013:
http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/handbook10-2-1
[11] Immunise Australia Program. Immunisation Related Payments for Parents. (Webpage dated 12 September 2013):
http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/related-payments
[12] Immunisation exemption: Medical contraindication form:
http://www.humanservices.gov.au/spw/customer/forms/resources/immu11.1310p.pdf on the Department of Human Services website: http://www.humanservices.gov.au/customer/forms/immu11
[13] Immunisation exemption: Conscientious objection form:
http://www.humanservices.gov.au/spw/customer/forms/resources/immu12-1302en.pdf on the Department of Human Services website: http://www.humanservices.gov.au/customer/forms/immu12
[14] Adverse event information for medicines and medical devices can be accessed in the TGA's Database of Adverse Notifications (DAEN): http://www.tga.gov.au/safety/daen.htm#.UyjVXfmSz-t
[15] National Immunisation Program Schedule from 1 July 2013:
http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/nips-ctn
[16] ***"Adverse event reports from consumers and health professionals to the TGA are voluntary, so there is under-reporting by these groups of adverse events related to therapeutic goods in Australia. This is the same around the world."*** About the DAEN – medicines: http://www.tga.gov.au/safety/daen-about.htm#.UyglSfmSz-t
[17] Demicheli V, Rivetti A, Debalini MG, Di Pietrantonj C. Vaccines for measles, mumps and rubella in children. Cochrane Database of Systematic Reviews 2012, Issue 2. Art. No.: CD004407. DOI: 10.1002/14651858.CD004407.pub3.
http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD004407.pub3/abstract
[18] See page 7 under "Serological Testing to Determine the Duration of Immunity (DOI)" in Day, M.J., Horzinek, M.C., Schultz, R.D. World Small Animal Veterinary Association's (WSAVA) Guidelines for the Vaccination of Dogs and Cats. Journal of Small Animal Practice. Vol. 51. June 2010:
http://www.wsava.org/sites/default/files/VaccinationGuidelines2010.pdf