Elizabeth Hart
Adelaide, South Australia
eliz.hart25@gmail.com

28 June 2012

The Hon Tanya Plibersek MP
Australian Federal Minister for Health

Minister Plibersek

Re: Questions re the Ethics of Australian Government Mandated Vaccination

The Australian Government recently announced that "families will now need to have their children fully immunised to receive the existing $726 per child Family Tax Benefit Part A supplement".[1]

The Government's definition of 'fully immunised' for the Family Tax Benefit Part A Supplement" states that children should be vaccinated with measles/mumps/rubella vaccine at 12 months and 4 years from 1 July 2012, and at 12 months and 18 months from 1 July 2013.[2]

I question the Government's requirement that children be vaccinated twice with the measles/mumps/rubella (MMR) vaccine as it is likely most children will already have lifelong immunity after the first dose. In this regard, I pose the following questions:

1. Is it ethical that government immunisation schedules in countries such as Australia[3], the US[4] and the UK[5] 'recommend' two doses of MMR vaccine, which results in many already immune individuals being needlessly revaccinated?

2. Have safety studies been undertaken in regard to having the second MMR (and MMR + Varicella) vaccine at 18 months, i.e. six months after the first vaccination at 12 months, rather than at four years?

3. Are the parents of children being informed that one dose of MMR vaccine is likely to confer lifelong immunity, particularly for measles and rubella? Are they being offered the opportunity to sign a consent form that includes this information?

4. Are people being offered the option of serological testing to verify a response to the vaccine?

5. Is it ethical for the Australian Government to withhold Family Tax Benefits from families who refuse to have their already immune children revaccinated?

In a paper published in 2009 discussing the potential impacts of schedule changes, waning immunity and vaccine uptake on measles elimination in Australia, James Wood et al state:

> "One-dose MMR coverage of 96% or greater maintained elimination more effectively than modelled changes in scheduling, **suggesting that maximising one-dose MMR coverage should be the highest priority**".[6]
> (My emphasis.)

Surely the emphasis should be on safely and effectively immunising more children with one dose of MMR vaccine, rather than needlessly revaccinating already immune children with a second dose at 18 months or four years?

In regards to the effectiveness of a single dose of MMR vaccine, a US Centers for Disease Control and Prevention (CDC) report dated May 1998 [7], advises: "Measles antibodies develop among approximately 95% of children vaccinated at age 12 months and 98% of children vaccinated at age 15 months (CDC, unpublished data)…Although vaccination produces lower antibody levels than natural disease, both serologic and epidemiologic evidence indicate that the vaccine induces long-term - probably lifelong - immunity, in most persons". In regards to rubella, the CDC advises: "In clinical trials, greater than or equal to 95% of susceptible persons aged greater than or equal to 12 months who received a single dose of strain RA 27/3 rubella vaccine developed serologic evidence of immunity…Follow-up studies indicate that one dose of vaccine confers long-term - probably lifelong - protection".

The situation for mumps is not quite so clear cut, although the CDC report does acknowledge that "more than 97% of persons who are susceptible to mumps develop measurable antibody following vaccination and, in controlled clinical trials, one dose of vaccine was approximately 95% efficacious in preventing mumps disease… The duration of vaccine-induced immunity is unknown, but serologic and epidemiologic data collected during 30 years of live vaccine use indicate both the persistence of antibody and continuing protection against infection".

According to the Product Information sheet for GlaxoSmithKline's PRIORIX measles/mumps/rubella live vaccine[8] sold in Australia, "in previously seronegative vaccinees, antibodies were detected in 98.0%, 96.1% and 99.3% of subjects against measles, mumps and rubella respectively".

The Cochrane Collaboration's systematic review of MMR vaccination[9] reports that "based on the available evidence, one MMR vaccine dose is at least 95% effective in preventing clinical measles and 92% effective in preventing secondary cases among household contacts". The Cochrane review also notes that: "The design and reporting of safety outcomes in MMR vaccine studies, both pre- and post-marketing, are largely inadequate."

Despite the reported effectiveness of the first MMR vaccine dose, the GSK PRIORIX Consumer Medicine Information leaflet[10], as approved by the Australian Therapeutic Goods Administration (TGA), states two doses are to be given. i.e.: "The first dose of PRIORIX is generally given to children at 12 months of age. A second dose is then administered to children at 4-6 years of age; preferably before commencement at school."

The CDC notes that: "The purpose of the two dose vaccination schedule is to produce immunity in the small proportion of persons who fail to respond immunologically to one or more of the components of the first dose."

If the GSK PRIORIX MMR vaccine is as effective as stated, **I question why a second vaccination is mandated for all children, particularly given the controversy surrounding the MMR vaccine.**

The second dose is not a 'booster' and it is misleading to use this term to describe the second MMR vaccination, although this description appears to be widespread. For example, the Victorian Department of Health website on "Immunisation – measles, mumps rubella"[11] states that: "A ***booster*** dose of the vaccine is given at four years of age." (My emphasis.)

Given that, according to the Cochrane Collaboration, the CDC, and the GSK PRIORIX Product Information sheet, most people vaccinated with one dose of MMR vaccine will be immune, I question the ethics of mass revaccination of already immune populations with misleadingly termed 'boosters' "to produce immunity in the small proportion of persons who fail to respond immunologically to one or more of the components of the first dose". This amounts to unnecessary vaccination, or 'over-vaccination', of people, in particular young children. **As a second dose provides no benefit to the already immune individual, this means they are undergoing the risks of vaccination for no benefit.**

By way of background to my interest in this subject, I have been investigating companion animal vaccination[12], in particular repeated annual or triennial vaccination of dogs with modified live virus (MLV) vaccines for parvovirus, distemper virus and adenovirus. I suggest it is useful to compare companion animal and human vaccination from a 'One Health'[13] perspective. Vaccine manufacturers and many veterinarians insist on repeatedly revaccinating dogs with MLV vaccines even though there is no evidence to support this practice. The World Small Animal Veterinary Association's (WSAVA) Guidelines for the Vaccination of Dogs and Cats (2010)[14] advise that puppies that are effectively vaccinated and immunised with these MLV vaccines are likely to have many years of immunity that "may be up to the lifetime of the pet". One of the authors of the WSAVA 2010 guidelines, Professor Ronald Schultz, makes the comparison with vaccination in humans and subsequent lifelong protection.[15] (Professor Schultz discusses duration of immunity further in the paper "Age and Long-term Protective Immunity in Dogs and Cats"[16].)

The WSAVA 2010 guidelines acknowledge that:

> **"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'".**

A document reporting on a roundtable discussion on companion animal vaccination and titre testing[17], published in 2002, provides interesting food for thought. For example, academics and veterinarians participating in the roundtable discussion raise concern about over-vaccination of companion animals and its possible connection with immune-mediated hemolytic anemia, thrombocytopenia, polyarthritis, atopy, chronic allergies, asthma etc. I suggest this document could also be usefully considered in regards to human vaccination and a possible connection with allergies, which have been reported to have hit "epidemic proportions" in Australia[18] [19] [20] [21] [22], and other health problems in humans. **While it may be difficult to prove a connection, surely it would be prudent to reduce unnecessary vaccination to avoid any risk?**

Laboratory and in-clinic titre testing is now available for companion animals (although many veterinarians remain reluctant to inform their clients of this option as it threatens the "convenient income generator"[23] of regular revaccination.)

If testing for antibody status is being recognised as best evidence-based practice for dogs and cats, surely parents of small children and others should be made aware of this option? For instance a recent article in *The Sunday Telegraph* titled "Parents fight it out in tussle over child jabs"[24] reports on a bitter tug-of-war over whether a six year old girl should be vaccinated. The article provides no information as to whether the child was vaccinated as an infant. Have the parents been offered the opportunity to have serological testing of their child to ascertain immunity status?

Minister Plibersek, there is concern within the community about the ever-increasing number of vaccines and repeat vaccinations being 'recommended' for children, and in effect mandated by the Government, leading to the rise of organisations such as The Australian Vaccination Network (AVN)[25], Jabs[26] in the UK, and the National Vaccine Information Center (NVIC)[27] in the US. A growing number of families are now refusing any vaccination.

There appears to be little consultation with the general community about additions to the vaccination schedule, and there are concerns about potential conflicts of interest[28] of government health advisors in this area. This issue has been polarised between 'pro' and 'anti' vaccination factions[29], with any questioning of the vaccination status quo being regarded as taboo. **Citizens must be allowed to have a rational debate on this issue to ensure public confidence in the Government's immunisation program, a program which should be transparently evidence-based.**

In the first instance, I suggest mandated vaccination of already immune individuals should be subject to urgent investigation on ethical and legal grounds.

I would appreciate your early response on this matter to my email address: eliz.hart25@gmail.com .

Yours sincerely
Elizabeth Hart

cc:
Professor Terry Nolan, Chair, Australian Technical Advisory Group on Immunisation (ATAGI)
Professor Peter Collingnon, Director of Infectious Diseases & Microbiology, ACT Government Health
Professor Robert Booy, Head of Clinical Research, National Centre for Immunisation Research & Surveillance
Laureate Professor Peter Doherty, Microbiology and Immunology, University of Melbourne
Dr James Wood, School of Public Health & Community Medicine, University of New South Wales
Dr Vittorio Demicheli, Cochrane Vaccines Field
Professor Andrew Kemp, Paediatrics & Child Health, Children's Hospital, Westmead
A/Professor Katie Allen, Theme Director Environment, Genes & Health Group Leader Gastro & Food Allergy, Murdoch Children's Research Institute
Dr Raymond Mullins, Immediate Past President, Australasian Society of Clinical Immunology and Allergy
Professor Ronald Schultz and Professor Michael Day, WSAVA Vaccination Guidelines Group
Professor Brian Martin, Social Sciences, University of Wollongong

References:
(Links current as at 27 June 2012)

[1] Strengthening Immunisation for Children. Immunise Australia Program. Australian Government Department of Health and Ageing: http://immunise.health.gov.au/internet/immunise/publishing.nsf/Content/factsheet-strengthening-immunisation
[2] Frequent Asked Questions: Changes to National Immunisation Schedule and Related Payments. Immunise Australia Program. Australian Government Department of Health and Ageing: http://immunise.health.gov.au/internet/immunise/publishing.nsf/Content/faq-related-payments#immunised
[3] National Immunisation Program Schedule. Immunise Australia Program. Australian Government Department of Health and Ageing: http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/nips2
[4] Recommended immunization schedule for persons aged 0 through 6 years—United States, 2012. Department of Health and Human Services. Centers for Disease Control and Prevention: http://www.cdc.gov/vaccines/schedules/downloads/child/0-6yrs-schedule-pr.pdf
[5] NHS Vaccination Checklist (UK): http://www.nhs.uk/Planners/vaccinations/Pages/Vaccinationchecklist.aspx
[6] Wood, JG, Gidding, HF et al. Potential impacts of schedule changes, waning immunity and vaccine uptake on measles elimination in Australia. Vaccine 27 (2009) 313-318.
[7] Measles, Mumps, and Rubella -- Vaccine Use and Strategies for Elimination of Measles, Rubella, and Congenital Rubella Syndrome and Control of Mumps: Recommendations of the Advisory Committee on Immunization Practices (ACIP), CDC MMWR May 22, 1998 / 47(RR-8);1-57: http://www.cdc.gov/mmwr/preview/mmwrhtml/00053391.htm
[8] GlaxoSmithKline PRIORIX Product Information: https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2010-PI-05279-3

[9] 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
[10] GlaxoSmithKline PRIORIX Consumer Medicine Information leaflet: https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2010-CMI-05278-3
[11] Immunisation – measles/mumps/rubella. Department of Health, Victoria: http://www.health.vic.gov.au/immunisation/factsheets/mmr.htm
[12] I have been researching and campaigning on companion animal vaccination for the past nearly four years. My open letter to the Australian Veterinary Association, Australasian Veterinary Boards Council and Australian Pesticides and Veterinary Medicines Authority, dated 26 March 2011, provides some background: http://users.on.net/~peter.hart/Open_letter_to_the_AVA_AVBC_APVMA_and_others_March_2011.pdf
[13] "One Health Initiative will unite human and veterinary medicine": http://www.onehealthinitiative.com/
[14] 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/PDF/Misc/VaccinationGuidelines2010.pdf
[15] Schultz, R.D. 1998. Current and future canine and feline vaccination programs. Veterinary Medicine. March 1998, 233-254.
[16] Schultz, R.D. et al. Age and Long-term Protective Immunity in Dogs and Cats. J. Com. Path. 2010, Vol. 142, S102-S108.
[17] Titer Testing and Vaccination: A New Look at Traditional Practices. A Roundtable Discussion. Veterinary Healthcare Communications, Lenexa, Kansas 2002: http://www.synbiotics.com/Products/CompanionAnimals/Canine/TiterCHEK-CDV-CPV-TiterTesting/96-0460-RoundTableDiscussion.pdf
[1818] Child allergy rates at 'epidemic proportions'. Sydney Morning Herald, 9 March 2010: http://www.smh.com.au/national/child-allergy-rates-at-epidemic-proportions-20100309-pus2.html
[19] Chain reaction – In less than a generation, food allergies in children – some of them potentially fatal – have reached epidemic levels. GoodWeekend, 23 July 2011.
[20] Kemp, AS, Mullins, RJ, Weiner, JM. The allergy epidemic: what is the Australian response? Medical Journal of Australia. Vol. 185, No. 4, 21 August 2006.
[21] Food Allergy. The Health Report, ABC Radio National: http://www.abc.net.au/radionational/programs/healthreport/food-allergy/2954588
[22] HealthNuts Research Update 2011. Murdoch Children's Research Institute: http://www.mcri.edu.au/media/55207/newsletter_2011_06_04.pdf
[23] A term used by Alan Radford in the Journal of Small Animal Practice's editorial discussing the updated WSAVA 2010 guidelines: The hitchhiker's guide to dog and cat vaccination. Journal of Small Animal Practice. June 2010. Vol. 51, Issue 6, pp293-294.
[24] Parents fight it out in tussle over child jabs. The Sunday Telegraph, 24 June 2012: http://www.news.com.au/national/parents-in-a-legal-tussle-on-child-jabs/story-e6frfkvr-1226406590503
[25] Australian Vaccination Network: http://avn.org.au/
[26] Jabs: Justice Awareness and Basic Support: http://www.jabs.org.uk/
[27] National Vaccine Information Center: http://www.nvic.org/
[28] Pharma conflicts must be disclosed. The Australian, 25 June 2012: http://www.theaustralian.com.au/national-affairs/health/pharma-conflicts-must-be-disclosed/story-fn59nokw-1226407029505
[29] See, for example: Martin, Brian. Debating vaccination: understanding the attack on the Australian Vaccination Network. Living Wisdom, Issue 8, February 2011, pp14-40: http://www.bmartin.cc/pubs/11LivingWisdom.html