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An open letter to: 25 May 2016
Professor Chris Baggoley
Chief Medical Officer
Australian Government Department of Health

Professor Baggoley

RE: MISLEADING INFORMATION ON ALUMINIUM AND VACCINE SAFETY AND VACCINATION POLICY

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 urgently address what I suggest are misleading statements on aluminium and vaccine safety** in ***The Australian Immunisation Handbook*** and the National Centre for Immunisation Research & Surveillance (NCIRS) **Fact Sheet on Vaccine Components**, and other publications, as detailed in the background information below.

Action must be taken to address these categorical statements which discount concerns about aluminium and vaccine safety. These statements are influential on vaccination policy, but I suggest **they have been based on unsound science, i.e. a poorly evidenced systematic review which categorically defends the use of aluminium-adjuvanted vaccines, co-authored by members of the Cochrane Vaccines Field, i.e. Tom Jefferson et al, and published in *The Lancet Infectious Diseases* journal in 2004.**[1]

In a letter challenging Jefferson et al's review, published in *The Lancet Infectious Diseases* in 2004, Professor Christopher Exley, a biologist with a PhD in the ecotoxicology of aluminium[2], states: *"There is no consensus as to whether it is safe to introduce aluminium in prophylaxis or otherwise,* ***and until the requisite research is carried out it is misleading to conclude that aluminium adjuvants are safe for all to use***."[3] (My emphasis.)

Professor Exley followed up with another letter to *The Lancet Infectious Diseases* in 2006 warning: ***"It is my opinion that substantially increased use of aluminium-adsorbed vaccines should be put on hold until research has demonstrated their safety, if not to all then to most individuals."***[4]

This is an important matter as Professor Exley's warning was ignored and in recent years a burgeoning number of aluminium-adjuvanted vaccine products and revaccinations has been added to the vaccination schedule in Australia, and around the world, e.g. multiple doses of diphtheria, tetanus and pertussis (dtap) vaccines and multiple doses of human papillomavirus (HPV) vaccines, among others. The long-term cumulative effects of the ever-increasing vaccine load are unknown.

Another dose of diphtheria, tetanus and pertussis vaccine has been added to Australia's National Immunisation Program Schedule since the implementation of the Australian Government's coercive No Jab, No Pay law in January 2016 (i.e. for 18 month old babies, in addition to dtap vaccinations already scheduled at 2, 4 and 6 months, 4 years, and between 10-15 years[5], plus recommended revaccination for pregnant women, household contacts of infants and healthcare workers[6], i.e. lifetime revaccination with dtap vaccines).

There has also been lobbying for the addition of the aluminium-adjuvanted Bexsero meningococcal B vaccine to the Australian vaccination schedule.[7] This vaccine product has been implemented in the UK under questionable circumstances (i.e. the conflicts of interest of the Chair of the UK Joint Committee on Vaccination and Immunisation, Professor Andrew Pollard, who was involved in the development of the Bexsero vaccine[8]), although I understand at this time it remains rejected by the Australian Pharmaceutical Benefits Advisory Committee.[9]

Background

Professor Baggoley, publications influential on vaccination policy in Australia include categorical statements on the safety of aluminium in vaccine products. For example, **Appendix 4 of The Australian Immunisation Handbook – Commonly asked questions about vaccination** states: *"A review of all available studies of aluminium-containing diphtheria, tetanus and pertussis vaccines (either alone or in combination)* ***found no evidence that aluminium salts in vaccines cause any serious or long-term adverse events****."*[10] (My emphasis.)

The **NCIRS Fact Sheet on Vaccine Components** makes a similar statement, i.e. *"Aluminium salts, in small amounts, have been added to certain vaccines for about 60 years and a recent review of all the available studies of aluminium-containing diphtheria, tetanus and pertussis vaccines (either alone or in combination)* ***found that there was no evidence that aluminium salts in vaccines cause any serious or long-term adverse events****."*[11] (My emphasis.)

Other papers and articles defending the use of aluminium adjuvants in vaccines make similar statements see for example O'Hagan and Rappuoli[12]; Eldred and Dean et al[13]; Nolan and Richmond et al[14]; and WebMD's article **Aluminium in Vaccines Poses No Harm**[15].

These categorical statements on the safety of aluminium in vaccines are based on the review paper **Adverse events after immunisation with aluminium-containing DTP vaccines: systematic review of the evidence**, co-authored by Tom Jefferson, Melanie Rudin and Carlo Di Pietrantonj of the Cochrane Vaccines Field, and published (*behind the paywall*) in *The Lancet Infectious Diseases* journal in 2004.[16]

Jefferson et al conclude in the abstract of this review: *"We found no evidence that aluminium salts in vaccines cause any serious or long-lasting adverse events.* ***Despite a lack of good-quality evidence we do not recommend that any further research on this topic is undertaken."*** (My emphasis.)

In their review Jefferson et al admit that: *"**Overall, the methodological quality of included studies was low.**"* And yet *"**despite a lack of good-quality evidence**"* Jefferson et al advise *"**we do not recommend that any further research on this topic is undertaken**"*.

This recommendation is bizarre, particularly as in an interview in 2002 with the UK newspaper *The Telegraph* titled **Vaccines expert warns studies are useless**[17], review author Tom Jefferson reportedly warned: ***"Most safety studies on childhood vaccines have not been conducted thoroughly enough to tell whether the jabs cause side effects"***. Dr Jefferson said: ***"There is some good research, but it is overwhelmed by the bad. The public has been let down because the proper studies have not been done"***, and he expressed his concern about future vaccination programmes including ***"five, six, even seven vaccines all at once"***. Which of course is exactly what happens now, see for example vaccination schedules in Australia[18], the US[19], and the UK[20].

Given Dr Jefferson's apparent earlier appreciation of the lack of sound studies on the risks and benefits of vaccine products, and his concern about future vaccination programmes including ***"five, six, even seven vaccines all at once"***, it is unaccountable that he and his colleagues could conclude in their strategic review on aluminium and vaccine safety ***"we do not recommend that any further research on this topic is undertaken"***.

It is also alarming that *The Lancet Infectious Diseases* published Jefferson et al's scientifically unsound review, which was self-admittedly based on studies of overall low methodological quality, and this raises questions about the effectiveness of the peer review process before publication.

In a letter published in *The Lancet Infectious Diseases* in June 2004[21] (*behind the paywall*) Professor Christopher Exley of Keele University raises concerns about Jefferson et al's review:

> *"I was surprised that the authors were able to conclude from their review that further research in this field was unnecessary. It would seem to me that this conclusion did not adequately reflect the findings of the limited resource base underpinning the review.* ***The authors criticised the quality of the data they had available to them and yet these data were still deemed sufficient to support such a strong conclusion. In addition, the authors made no reference to the fact that aluminium-based adjuvants contribute to the recipients systemic body burden of aluminium. We now know that aluminium in adjuvants is dissolved and transported throughout the body, including the brain***[22] ***and we cannot discount the biological availability of this aluminium. It is a sobering thought that aluminium adjuvants have not had to pass any of the safety trials that would be expected of any drug or treatment.*** *Their application is historical and this should not necessarily be equated with their safety. There is no consensus as to whether it is safe to introduce aluminium in prophylaxis or otherwise****, and until the requisite research is carried out it is misleading to conclude that aluminium adjuvants are safe for all to use****."* (My emphasis.)

Professor Exley followed up with another letter published in *The Lancet Infectious Diseases* in April 2006[23] (*behind the paywall*) in which he states:

> *"In 2004, I commented in The Lancet Infectious Diseases that* ***it was too early to conclude that aluminium adjuvants were safe for all to use.***[24] ***This opinion has been strengthened by recent research highlighting delayed hypersensitivity to aluminium in children who have received aluminium-adsorbed vaccines.***[25,26] *Contact allergy to aluminium has been known for some time*[27]*, although delayed hypersensitivity to aluminium is a recently recognised phenomenon of unknown aetiology.* ***The observation that the body***

> ***retains a "memory" of previous exposure to aluminium (as an adjuvant) is intriguing and may support research that reported the development of anti-aluminium monoclonal antibodies.***[28] *Delayed hypersensitivity to aluminium raises a number of issues relating to the biological availability of this environmental toxin, perhaps not least of which, and pertinent to this moment in time, is the plan to improve the immunogenicity of (bird) flu vaccine by using aluminium-based adjuvants.*[29] ***It is my opinion that substantially increased use of aluminium-adsorbed vaccines should be put on hold until research has demonstrated their safety, if not to all then to most individuals."*** (My emphasis.)

Professor Exley's warning that ***"substantially increased use of aluminium-adsorbed vaccines should be put on hold until research has demonstrated their safety"*** has been ignored, with such vaccines being added to the vaccination schedule in Australia, and around the world, e.g. multiple doses of diphtheria, tetanus and pertussis vaccines, multiple doses of HPV vaccines, and the meningococcal B vaccine in the UK, which is also being lobbied for in Australia. **The long-term cumulative effects of the ever-increasing vaccine load are unknown.**

As shown by statements in ***The Australian Immunisation Handbook***, the **NCIRS Fact Sheet on Vaccine Components**, and other publications mentioned previously, Jefferson et al's review continues to be used to promote the idea that aluminium-adjuvanted vaccines are categorically safe.

I suggest Jefferson et al's review is poorly evidenced and scientifically unsound. It should not be used to support the safety of aluminium in vaccine products.

This is just one example of unreliable information being cited in documents influential on vaccination policy. The mind boggles at how many more poorly evidenced papers and reviews supporting the use of vaccine products might lurk within journals such as *The Lancet Infectious Diseases*, with such questionable information being cited and promulgated by organisations such as the National Centre for Immunisation Research & Surveillance, and government publications such as *The Australian Immunisation Handbook*.

Professor Baggoley, I request that you take urgent action to address the questionable references to Jefferson et al's review in publications influential on vaccination policy in Australia, e.g. *The Australian Immunisation Handbook* and the NCIRS Fact Sheet on Vaccine Components, and the consequences this has had for the National Immunisation Program Schedule. Jefferson et al's poorly evidenced review is likely to have had far-reaching impact on international vaccination policy, and steps must be taken to challenge *The Lancet Infectious Diseases* and Cochrane in this regard.

I request your early response on this matter. This is a matter of public interest, particularly in light of coercive vaccination policies implemented by the Australian Government. Please note this letter and your response will be circulated to other parties.

Sincerely

Elizabeth Hart
https://over-vaccination.net/

cc: Dr Tony Hobbs, Acting Chief Medical Officer
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

References:

[1] Jefferson T, Rudin M, Di Pietrantoni C. Adverse events after immunisation with aluminium-containing DTP vaccines: systematic review of the evidence. *Lancet Infect Dis*. 2004 Feb; 4(2):84-90.
[2] Professor Chris Exley, Keele University: https://www.keele.ac.uk/aluminium/groupmembers/chrisexley/
[3] Exley C. Aluminium-containing DTP vaccines. *Lancet Infect Dis* 2004; 4: 324.
[4] Exley C. Aluminium-adsorbed vaccines. *Lancet Infect Dis*. 2006; 6: 189.
[5] National Immunisation Program Schedule from February 2016.
[6] 4.12.7 Recommendations. Pertussis. The Australian Immunisation Handbook, 10th edition.
[7] See Call to fund Meningococcal B vaccine, Medical Observer, 27 July 2015 and Meningococcal B vax rejection a bad move: expert, Medical Observer, 24 August 2015.
[8] The GSK/Novartis Bexsero meningococcal B vaccine has been implemented in the UK in questionable circumstances, i.e. the conflicts of interest of the Chair of the UK Joint Committee on Vaccination and Immunisation, Professor Andrew Pollard, who was involved in the development of the Bexsero vaccine. This matter is ongoing. See for example this post by John

Stone: Bexsero: More Questions for the British and Scottish Governments Over Vaccine Committee Chair, published on the Age of Autism website, 5 January 2016. Also see Expert reaction to approval of meningitis B vaccine, published on the Oxford Vaccine Group, 16 November 2012; and Do we need a new approach to making vaccine recommendations? Controversy about the evidence, economics, ethics, lobbying, and decision making surrounding a new vaccine for serogroup B meningococcal disease should trigger change in the way we develop recommendations for new vaccines say Natasha Crowcroft and colleagues, BMJ 2015;350:h308; and Introducing a new group B meningococcus vaccine, BMJ 2014;348:g2415.

[9] The Bexsero meningococcal B vaccine has been rejected ***three times*** by the Australian Pharmaceutical Benefits Advisory Committee (PBAC) due to multiple uncertainties in relation to the clinical effectiveness of the vaccine against the disease and other reasons. (See Recommendations made by the PBAC July 2015 – Subsequent decisions not to recommend.) Despite this, members of the powerful 'vaccination clique' in Australia have continued to lobby for this vaccine to be added to the schedule in Australia. For example, Robert Booy uses the UK's adoption of the Bexsero meningococcal B vaccine to justify implementing the vaccine in Australia, saying *"Whatever reservations the PBAC has, they are not shared globally"*. (See Meningococcal B vax rejection a bad move: expert, Medical Observer, 24 August 2015.) Meanwhile, given the multiple uncertainties about the Bexsero meningococcal B vaccine, I question why the Therapeutic Goods Administration (TGA) allowed this vaccine product to be registered in the first place?

[10] The Australian Immunisation Handbook, 10th Edition. Appendix 4: Commonly asked questions about vaccination.

[11] Vaccines Component Fact Sheet, May 2013 (Content last updated February 2008). National Centre for Immunisation Research & Surveillance (NCIRS).

[12] A paper by Derek T. O'Hagan and Rino Rappuoli titled The safety of vaccines, published in *Drug Discovery Today* in 2004, states: *"A recent meta-analysis of the available safety data on alum could find no evidence of any serious long-lasting adverse effects."* (This paper is behind the paywall, US$27.95)

[13] A paper by Barbara E Eldred and Angela J Dean et al titled Vaccine components and constituents: responding to consumer concerns, published in the *Medical Journal of Australia* in 2006, states: *"A systematic review of controlled safety studies reported that vaccines containing aluminium produce more erythema and induration than other vaccines in young children (up to 18 months of age), and greater local pain in older children (10-18 years). No association was found between aluminium and more serious or long-term adverse effects."* (This paper is openly accessible on the MJA website.)

[14] A paper by Terry Nolan and Peter C Richmond et al titled Safety and immunogenicity of a prototype adjuvanted inactivated split-virus influenza A (H5N1) vaccine in infants and children, published in *Vaccine* in 2008, states: *"There is extensive and prolonged global experience of the safe use of aluminium adjuvanted vaccines in infants and children."* (Jefferson et al's review is referenced to support Nolan and Richmond et al's statement.) (This paper is behind the paywall, US$35.95.)

[15] An article titled Aluminium in Vaccines Poses No Harm**,** published on the industry-sponsored WebMD website (January 2004), promotes Jefferson et al's review and states: *"After scouring through all the available medical data, researchers in Rome say there is no evidence that aluminium – contained within the combined diphtheria, tetanus and pertussis vaccine commonly known as DTP and routinely given to children – poses any serious or long-term side effects."*

[16] Jefferson T, Rudin M, Di Pietrantoni C. Adverse events after immunisation with aluminium-containing DTP vaccines: systematic review of the evidence. *Lancet Infect Dis*. 2004 Feb; 4(2):84-90.

[17] Lorraine Fraser. Vaccines expert warns studies are useless. The Telegraph, 27 October 2002.

[18] National Immunisation Program Schedule from February 2016.

[19] Centers for Disease Control and Prevention. Immunization Schedules. Birth-18 Years & "Catch-up" Immunization Schedules, United States 2016.

[20] The NHS vaccination schedule.

[21] Exley C. Aluminium-containing DTP vaccines. *Lancet Infect Dis* 2004; 4: 324.

[22] Flarend R. Absorption of aluminium from antiperspirants and vaccine adjuvants. In: Exley C. ed. Aluminium and Alzheimer's disease. The science that describes the link. Amsterdam: Elsevier, 2001: 75-96.

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[24] Exley C. Aluminium-containing DTP vaccines. *Lancet Infect Dis* 2004; 4: 324.

[25] Bergfors E, Trollfors B, Inerot A. Unexpectedly high incidence of persistent itching nodules and delayed hypersensitivity to aluminium in children after the use of adsorbed vaccines from a single manufacturer. *Vaccine* 2003; 22: 64-69

[26] Bergfors E, Björkelund C, Trollfors B. Nineteen cases of persistent pruritic nodules and contact allergy to aluminium after injection of commonly used aluminium-adsorbed vaccines. *Eur J Pediatr* 2004; 164: 691-97.

[27] Bohler-Sommeregger K, Lindemayr H. Contact sensitivity to aluminium. *Contact Dermatitis* 1986; 15: 278-81.

[28] Levy R, Shohat L, Solomon B. Specificity of an anti-aluminium monoclonal antibody toward free and protein-bound aluminium. *J Inorg Biochem* 1998; 69: 159-63.

[29] Wadman M. Race is on for flu vaccine. *Nature* 2005; 438: 23.