

Petitioner Letter of 6 January 2016

**PE01574 – Response to Scottish Government**

The Scottish Government response has stated "medicine safety is a reserved matter" where the Medicines and Healthcare Products Regulatory Agency (MHRA) "acts on behalf of the whole of the UK..." Since the MHRA is acting on behalf of the entire population, they should have an obligation to provide any and all documentation used in their decision-making processes for independent analysis. People's health and thus the safety of medicines is everyone's business and cannot be a reserved matter without provisions for independent review. This is a crucial element in maintaining the public's trust.

The Scottish Government response also stated, "It would be unlikely that new evidence would be brought to light at the roundtable requested..." Allow me to present the following **significant points to consider**, most of which have arisen since the Scottish Government's response to PE01574 was issued:

- **Dr. Deirdre Little discovered** that vaccine constituents formed the placebo in all placebo controlled safety trials of Gardasil. Although use of a 'saline placebo' was claimed by Merck Sharp and Dohme, a saline placebo was not used in safety trials. The placebo in the only controlled safety trial for under 16-year olds (protocol 018) is misrepresented by Merck Sharpe and Dohme as saline in Product Information to all providers and consumers, and in licensing application review. Upon this author's request to the TGA (Australia) that Product Information be corrected, the **TGA requested Merck Sharpe and Dohme correct their product information.**
- According to Professor Chris Exley of Keele University, "Vaccine makers are consciously using aluminum adjuvant as placebo or control to ensure that they cover all of the serious side effects associated with aluminum adjuvant. So I think that one cannot say whether the HPV vaccine causes serious side effects or not and you can not say you have done placebo trials" (See article: by Jeppe Findalen and Maria Cuculiza, "Førende forsker: Forsøg med HPV-vaccinen skjuler alvorlige bivirkninger", MetroExpress, Danish Online Edition, 08/12/15).
- Christian Gluud is the head of the Copenhagen Trial Unit which provides advice on the outcomes of clinical trials. He states, "If it is correct that there were virtually no clinical studies conducted without aluminum adjuvant in the control group, we have a huge problem with respect to possible side effects. These so-called placebo vaccinations can hide possible side effects. **If the side effects from aluminum adjuvants are similar to some of the symptoms seen among the sick girls at the HPV intake centers, new studies should be required under the direction of independent clinical investigators as soon as possible.** Meanwhile, one should also consider stopping vaccinations against HPV."
- **It is claimed that HPV 16 and 18 are responsible for approximately 70% of cervical cancer cases** worldwide. Table 2 from an article entitled Estimation of HPV prevalence in young women in Scotland, by Kavanagh et al. in the *BMC Infectious Diseases* 2013, 13:519 (<http://www.biomedcentral.com/1471-2334/13/519>) clearly indicates **HPV types 16 and 18 are not the most prevalent high risk types in Scotland making HPV vaccines far less potentially effective in our country.** (See article by Kate Foster, "Cancer vaccine 'pointless'", Daily Record, Print Edition, page 47, 17/11/13).

**Extracted from Table 2 Weighted prevalence of HPV stratified by sample type**

HPV Type	Urine Sample	Self-collected Swab	Liquid-based Cytology
HPV 16 or 18	10%	16.6%	23%
High-risk types excluding 16 or 18	13.2%	20.6%	32.2%

- A case recently filed under the Vaccine Injury Compensation program in the United States contends a boy suffered from Myocarditis which was caused in fact by the Gardasil vaccine. Petitioners contend that the logical sequence of cause and effect show that the vaccination was the reason for the death. Further supportive of the causal relationship is established by looking to the proximate temporal relationship between the vaccination and the death. The fact that the deceased was a healthy 14 year old boy with no health problems is strong circumstantial evidence that the death was caused in fact by the Gardasil vaccine. See [Expert's report](#) at the request of the legal team acting for the family of the young boy.
- The expert witness in the case above was so disturbed by his findings that he felt compelled to publicly issue the following warning: ***Teenagers vaccinated with Gardasil® should stay away from competitive sports such as football for at least two months, and should have an electrocardiogram to rule out silent myocardial infarction if there is any incidence of syncope, chest discomfort, tachycardia or hypotension within two months after Gardasil® vaccination.***
- This concern is corroborated by the report of a case of fatal myocarditis in a 17-year-old woman one week after receiving Gardasil, published in [The American Journal of Medicine by Edgard Wehbe, MD](#), Department of Internal Medicine at the University of Kansas School of Medicine.
- On December 17 2015, the Danish Health Committee held an open discussion on the benefit/risk profile of HPV vaccines with participants from both sides of the scientific aisle. MPs and the public were allowed to put forth questions and current treatment options for the injured were discussed.
- The latest edition of [MedCheck: The Informed Prescriber](#), published by a non-profit group of scientists and medical professionals who have been analyzing medicines for 30 years, includes an article on HPV vaccines (see page 9). The conclusion of this article states: "As the harms of HPV vaccine became well known, many serious adverse reaction cases were reported long after injection including unprecedented "severe reactions", which were completely new even to specialists in neurology and collagen disease of childhood. Because the risk of autoimmune disease is estimated to be several hundred-times higher and even the excess fatalities higher than the maximum expected preventable cervical cancer death risk by several orders of ten; so, the harms are definitely unacceptable. **The MHLW (Japanese Ministry of Health, Labour and Welfare) and the manufacturers should admit the causality of the HPV vaccine in serious adverse reactions as soon as possible. HPV vaccine should be withdrawn from the market and all women inoculated with HPV vaccine should be followed up.**"
- 11 December 2015, Marie-Océane Bourguignon's solicitor, Jean-Christophe Coubris, filed a lawsuit with the head of the Paris Regional Healthcare Division's examining judges, against Sanofi Pasteur MSD labs and the French National Medicines Agency (ANSM), for involuntary assault on the integrity of a human person (See article: "Cancer du col de l'utérus : nouvelle plainte contre le Gardasil En savoir plus sur", Les Echos, French Online Edition, 11/12/15). This new lawsuit follows the refusal by the Paris Regional Healthcare Division's public prosecutor's department to deliver a verdict on the lawsuits of Marie-Océane Bourguignon and 33 other Gardasil victims. When a verdict was not handed down by the previous court, attorney Coubris felt it imperative to get the case referred to an examining judge with extensive powers of investigation. The Coubris, Courtois & Associates firm now represents 100 HPV vaccine survivors.
- One of Denmark's leading cancer experts, [Dr. Torben Palshof, writes his own assessment of the EMA's report on HPV vaccine safety](#). Clearly, the issue is not as cut and dried as the EMA would have people believe.
- Danish doctor [Louise Brinth responds](#) to the EMA's criticism of her work for HPV vaccine survivors at the Syncope Unit at Bispebjerg and Frederiksberg Hospital.
- A new documentary titled 'Cervical Vaccine: Is It Safe?' aired in Ireland on the 14th of December on TV3, one of the country's major mainstream television networks. This is the third mainstream media documentary calling into serious question the safety and effectiveness of the HPV vaccine in worldwide circulation. TD's Maureen O'Sullivan and Michael Moynihan

(Irish Politicians) are **calling for independent investigations into what is making so many girls ill after Gardasil injections and providing assistance to help them regain their health.**

- December 17, 2015 Brazil: The Federal Public Ministry (MPF) filed a civil action asking the **Federal Court to prohibit HPV vaccine administration across the country** (see article: "MPF pede proibição da vacina contra HPV em todo o país", Otempo, Online Edition, 17/12/15). The lawsuit also seeks the annulment of all legislative acts of the National Health Surveillance Agency (Anvisa), which authorized the import, production, distribution and marketing of the vaccine in the country.
- [During Gardasil 9 clinical trials a total of 23,266 subjects were vaccinated](#) in 7 clinical trials. In this small population, **there were a total of 5 cases of leukaemia** (4 exposed to 9vHPV and 1 exposed to qHPV) in a clinical safety database with 13,360 exposed to 9vHPV. A reasonable lower and upper boundary of acute leukaemia incidence (lymphoid and myeloid combined) in the 10-20 year old age is approximately 2 to 4 per 100,000 person-years. (page 114) **Occurrence of any further cases of leukaemia, with a main focus on the ongoing/planned studies, should be reported as a part of close monitoring of leukaemia in PSURs.** (page 117) **Are doctors being warned to look for this potential reaction?**

The Scottish Government response stated, "The evidence which has been reviewed, and continues to be reviewed, by the bodies from whom the Scottish Government and the other UK administrations take their advice, shows that the HPV vaccine has a good safety profile, and is effective."

A recent survey completed by 94 members of the UK Association of HPV Vaccine Injured Daughters (AHVID) at the request of the EMA yielded the following results about the yellow card reports:

- At least 22 cases have not been reported at all, including 4 with confirmed diagnosis of POTS.
- Approximately 858 doctors/specialists had been consulted but only 13 offered to file Yellow Cards.
- 89 of the 94 families were not aware of a Yellow Card System prior to or at the time of vaccination.
- 7 families had health professionals who refused to raise a Yellow Card.
- Only 10 of the 94 families had been contacted by the MHRA, typically for more details, not follow-up.

The above analysis gives but a glimpse into the woeful inadequacies of the system used by the MHRA to assure the Scottish Government, the UK Government and our citizens of the safety profile of HPV vaccines. Rather than providing reassurance, the above data gives an indication of the serious under-reporting of adverse events following HPV vaccinations and a lack of follow-up on cases which are reported. It is painfully obvious that the MHRA is not currently operating in the best interests of the public at large. In my opinion this is a true reflection of serious under-reporting and lack of follow-up within the MHRA and this will also reflect badly on the other bodies from whom the Scottish Government and the other UK administrations take their advice.

There is indeed an urgent need to discover why the MHRA seems content to act decisively on behalf of the entire UK population when they have so little hard data to back up their statements. After all, the whole purpose of the MHRA gathering statistics is to establish an honest reflection of events – something that is not available to anyone at the moment.

Therefore, a roundtable discussion between scientists and medical professionals from both sides of the debate is absolutely essential. Scottish politicians must have the opportunity to ask pertinent questions and get honest answers backed up with the latest scientific information available. Too many countries are questioning the safety of HPV vaccines and either taking legal action or

demanding the withdrawal of HPV vaccines until full independent investigations are completed. Not all of the citizens of the world affected by these vaccines can be wrong!

Albert Einstein once stated, "Condemnation before investigation is the highest form of ignorance." We cannot condemn the views of thousands of parents and a growing number of doctors, scientists and politicians without independent investigations and open debates.

**Freda Birrell, on behalf of  
UK Association of HPV Vaccine Injured Daughters (AHVID)**