1240/5(7965)

**WRITTEN QUESTION TO THE MINISTER FOR HEALTH AND SOCIAL SERVICES BY DEPUTY G.C.L. BAUDAINS OF ST. CLEMENT ANSWER TO BE TABLED ON TUESDAY 19th NOVEMBER 2013**

**Question**

Further to my recent question of 5th November 2013, regarding the Gardasil vaccine and its known side effects, would the Minister advise –

(a) how many strains of HPV exist and how many of those the vaccine is supposed to protect women from;

(b) whether she is aware of the reputation of the vaccine's manufacturer Merck in relation to another drug Vioxx;

(c) what research, if any, was undertaken by the Department into the alleged 'fast tracking' of Gardasil and reports made to the Vaccine Adverse Events Reporting System within two years of its release claiming incidents of death and serious health problems such as strokes, blood clots, cardiac arrests, seizures, fainting, and lupus and, if none, why;

(d) what research, if any, was undertaken by the Department into the accuracy of the that the trials of Gardasil and was the Department made aware whether the trials were financed by Merck; and,

(e) whether she is aware of and has studied research into Gardasil safety, such as that by the University of Columbia and, if not, why not?

**Answer**

a) There are at least 140 HPV types. Of these, some 13 cause cervical cancer and these are known as 'high risk HPV' types. Two high risk types cause 75% of all cervical cancers. The vaccine is over 99% effective at protecting women against these two high risk HPV types.

b) The Minister is aware that a medicine used to treat arthritis, called Vioxx, was withdrawn from use almost a decade ago by the American pharmaceutical manufacturer called Merck.

The Health and Social Services Department does not purchase its HPV vaccine from the US company, Merck.

The Health and Social Services Department purchases its HPV vaccine from the UK Department of Health Vaccine Supply Team, who in turn are supplied by

Sanofi Pasteur, only company in the UK totally dedicated to the manufacture of vaccines.

Merck (USA) is one of the companies which form the Sanofi Pasteur MSD conglomerate. However, it is not involved in the supply of vaccines to the Health and Social Services Department.

The Health and Social Services Department is aware of internet based allegations of fast-tracking against the American Food and Drug Administration (FDA). The Health and Social Services Department is not, however, the UK medicines/vaccine Regulator. It is not, therefore, engaged in researching allegations, nor investigating reports, made to the American Vaccine Adverse Events Reporting System (VAERS), which is a United States database managed by the American Food and Drug Administration (FDA).

The Health and Social Services Department is not a primary research body and, as such, when making decisions about offering vaccines in Jersey, the Department looks to the professional, primary research bodies, including the UK Joint Committee on Vaccination and Immunisation, the UK Department of Health, the European Medicines Agency and to the highly reputable, independent UK Regulator, the Medicines and Healthcare Products Regulatory Agency (MHRA).

All vaccines undergo rigorous testing before being approved for use and the MHRA monitors all medicines and vaccines after they come into widespread use.

Almost 100 million doses of Gardasil have been given safely in over 120 countries, and the MHRA has confirmed there have been no major safety issues with this vaccine.

c) /e) The Health and Social Services Department is neither a regulatory nor an investigatory body in the context of medicine/ vaccine data evaluation. It has not, therefore, undertaken investigation of primary research into the efficacy of Gardasil. Nor has it undertaken investigation into any research that may have been conducted by the University of Columbia, or indeed, any other academic institute, about this or any other medicine or vaccine

Research, which critically appraises the accuracy of trials of any medicine/ vaccine, forms part of the UK Regulatory role, a function performed by the UK MHRA.

Employing over 900 people, the MRHA independently and impartially examines clinical trial data, assuring itself of the validity of the trials, the quality of the trials data, and the safety and efficacy of the medicine/vaccine, before granting a licence.

It is both reasonable and appropriate, therefore, that the Health and Social Services Department seeks its expert guidance on approved medicines/vaccine from the official, independent regulator, and not via Google search.

As it has no role in the regulation of vaccine trials, there is no reason why the Health and Social Services Department would know, or need to know, how or where the funding for conducting clinical trials is sourced. Nevertheless, medical academia is well used to contractual collaboration which ensures independence of research findings and few, if any, professional experts would believe that the UK medicines regulator fails to reassure itself of the integrity of research data.

The MHRA advises that Gardasil is a highly effective anti-cancer vaccine.

Fully satisfied by the expert guidance of the MRHA, it is the duty and responsibility of health services to offer the cervical cancer vaccine to girls and young women in the island.

But Jersey doesn't have compulsory vaccination and it is for the individual, together with their parents or guardians, to decide whether they are prepared to take up the offer of protection against two virulent, and potentially fatal, HPVs.

These HPVs are responsible for over 75% of all cervical cancer cases, tragically claiming the lives of women every year.