MINISTRY OF HEALTH
MANATŪ HAUORA

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Ref. No _____

28 October 2011

[redacted]

Dear [redacted]

Thank you for your email of 30 September 2011 requesting information on Gardasil and recombinant HBV vaccine from Merck. I have treated your request for information as a request made under the Official Information Act 1982 (the Act). I will respond to each of your requests in the order in which you have asked them.

I would also like to clarify a misunderstanding that appears to have arisen. Medsafe wrote to you previously to state that it does not sign confidentiality agreements with third parties. I can confirm that Medsafe does not sign confidentiality agreements with pharmaceutical companies. When requested to release information under the Act Medsafe is guided by the Act. The Act clearly sets out why information is withheld and the Ombudsman's office also publishes guidance in relation to the withholding of information. Medsafe complies with the legislation when asked to release information under the Act. Information may be withheld for different reasons dependant on the type of information.

1 *Provide evidence showing when Medsafe ruled that recombinant HBV/HPV DNA to be an expected ingredient in both the Hepatitis B and Gardasil vaccine.*

Recombinant DNA is not an ingredient of either hepatitis B vaccine or Gardasil vaccine. The presence of residual DNA in Gardasil vaccine was evaluated before consent to distribute was granted in New Zealand, as part of the consideration of the purification process. A *copy* of the Medsafe evaluation report, previously released under the Act is enclosed. Some information within this report is withheld under section 9 (2)(b)(i) of the Act to protect trade secrets. No evaluation report is held by Medsafe for Merck recombinant HBV vaccine (HBvaxPRO), since it was not Medsafe practice to produce full evaluation reports in 1987 when this vaccine was first given consent to distribute.

2 *Provide the information supplied to you from Merck relating to both Gardasil and the recombinant hepatitis B vaccine, that both these vaccines were known by them at the time of licensure to contain expected fragments of recombinant DNA.*

Medicines in New Zealand are not licensed. The Minister of Health may grant a pharmaceutical consent to distribute a medicine in New Zealand. The presence of recombinant DNA fragments was known before Gardasil was granted consent to distribute in New Zealand. The information provided by Merck is already included in the report provided in answer to question 1. With regard to HBV vaccine, Merck provided information about DNA for Comvax, when the company applied for consent to distribute this vaccine in New Zealand in 1999. From this point any changes in quality aspects relating to HBV applied to both vaccines (Comvax and HBvaxPRO). The relevant extracts from the dossier are enclosed. Please note that information relating to other aspects of this vaccine has been removed. Some information within this report is withheld under section 9 (2)(b)(i) of the Act to protect trade secrets.

3 *Provide documentation provided by Merck showing the level of residual rHPV DNA considered 'safe', the studies proving that, and what the level measure post manufacturing were for both hepatitis B and Gardasil vaccines.*

Information on the safety of recombinant DNA technology in medicines is publically available. Medsafe follows the guidance issued by other medicines regulators when evaluating the safety of these medicines. This guidance details the test which should be performed and the acceptable quality limits that should be applied to these medicines. This information is publically available.

Medsafe does not hold specific information provided by Merck on safe levels of residual recombinant DNA in medicines. I am therefore refusing your request under the provisions of section 18(e) of the Act because the documents containing the information requested do not exist.

Medsafe does not hold information on levels of DNA measured after manufacture for recombinant HBV vaccine from Merck other than that already provided in response to question 2. The results of routine testing of these levels are not required to be filed with Medsafe.

Information on levels of DNA measured after manufacture for Gardasil vaccines provided to Medsafe by Merck is withheld under: section 9(2)(b)(i) of the Act as this is considered a trade secret; and under section 9 (2)(ba)(i) of the Act as release of this information would be likely to prejudice the supply of similar information and it is in the public interest that such information should continue to be supplied.

You have the right under section 28(3) of the Act to ask the Ombudsman to investigate and review my decision not to release any of the information withheld.

Yours sincerely

Dr Don Mackie
Chief Medical Officer
Clinical Leadership, Protection and Regulation