



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Freda Birrell
Sane Vax Inc.

22 September 2011
EMA/771987/2011

Subject: Sane Vax Inc. letter concerning Gardasil

Dear Ms Birrell,

Thank you for sharing your information concerning the Gardasil vaccine with the Committee for Medicinal Products for Human Use (CHMP).

The CHMP takes very seriously any potential contamination issue and has considered all the available evidence in relation to the statements you have made about Gardasil in relation to HPV DNA. Following your letter, information concerning the risk was immediately requested from the EU marketing authorisation holder (Sanofi Pasteur MSD, SNC). The issue was then discussed in detail by the Biologics Working Party (BWP) at its meeting of 12-14 September and by the CHMP at its meeting of 19-22 September.

The CHMP came to the following conclusions regarding the Gardasil vaccine.

The Committee noted that the presence of recombinant DNA fragments does not represent a case of contamination and is not considered to be a risk to vaccine recipients. All medicinal products manufactured using recombinant technology may contain small fragments of residual DNA.

In Gardasil, residual DNA originates from the recombinant expression system used in the production of the vaccine (yeast cells or plasmids). It is highly fragmented, with no ability to replicate and therefore no infectious capacity. Furthermore, the amount of these residual substances is minimised by robust manufacturing processes.

The information brought to the attention of the CHMP by Sane Vax Inc. is not considered to provide new information about the quality of the vaccine.

Concerning the highlighted case of Juvenile Rheumatoid Arthritis observed in association with a third dose of Gardasil, the information is very limited. In view of the total number of doses of Gardasil distributed since launch in 2006, i.e. more than 79 million doses worldwide, this case might well be within the expected number of Juvenile Rheumatoid Arthritis cases in the vaccinated population but coinciding with vaccination.

In summary, the current benefit-risk balance of Gardasil is not considered to be affected by the information reported by Sane Vax Inc. and Gardasil is considered to remain safe and effective.

Yours sincerely,

Dr Eric Abadie, Chairman of the CHMP
On behalf of the CHMP

