

Notice Information: Human Medicines - Advisory 24 January 2008

Part 1. Product Information		
a)	Title:	EMEA Statement on the safety of Gardasil

b) Product Name/Type: Gardasil

c) Active Substance: Human Papillomavirus Vaccine

Part 2. Problem/Issue

a) Problem/Issue:

The European Medicines Agency (EMEA) has issued a statement on the safety of Gardasil following reports of deaths in women who had previously received the vaccine, including two cases which occurred in the European Union (Austria and Germany). The EU cases were reported as part of the continuous monitoring of the safety of medicines. In both cases, the cause of death was not identified and a causal relationship between administration of Gardasil and the deaths of the women has not been established. On the basis of the currently available information, the EMEA's Committee for Medicinal Products for Human Use is of the opinion that the benefits of Gardasil continue to outweigh its risks and that no changes to the product information are necessary. For further Information, Click here To view the Press Release

Part 3. Keywords

a) Keywords: Gardasil