Malta, 25 January 2008

Circular No. P02/2008

Dear Healthcare Professional,

Re: Safety of Gardasil® (quadrivalent human papillomavirus vaccine).

Following the receipt of two European reports of sudden deaths associated with the administration of Gardasil®, as part of the continuous monitoring of the safety of medicines, the Committee for Medicinal Products for Human Use (CHMP) has issued a press release stating that the benefit risk balance of this medicinal product is still **positive**, and that currently no changes to the product information is necessary. The Medicines Authority has participated in these discussions held at the European Medicines Agency (EMEA) and is in agreement with the **press release** issued by the EMEA, attached here for your perusal.

The Medicines Authority will notify health care professionals (HCPs) and patients in a timely fashion as new information becomes available. HCPs are urged to report Adverse Drug Reactions (ADRs) associated with this product to the Medicines Authority by filling an ADR Reporting Form. This can be accessed at:
http://www.medicinesauthority.gov.mt/pub/adr.doc

Please note that an identical quadrivalent human papillomavirus vaccine is marketed as Silgard® in the EU. HCPs are urged to report ADRs also for this product.

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