HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

HPRA confirms no patient fatality in Ireland associated with Gardasil

Following commentary on social media (beginning 20 January 2020), this statement has been issued to provide clarification concerning a report that was submitted in error to the HPRA, as follows:

- A report of a suspected side effect was submitted by the marketing authorisation holder for Gardasil to the European Medicines Agency (EMA) safety database (Eudravigilance) and to the HPRA on 27 December 2019. The report was based on a remark observed on a social media site and was initially understood to relate to a fatality of a patient in Ireland.
- The social media remark included wording to the effect that the fatality was 'Gardasil related'. No additional relevant information was provided. On receipt of the report, the HPRA followed up with the marketing authorisation holder to request further details.
- Meanwhile, a request for a listing of reports received by the HPRA and associated with Gardasil was made by a member of the public. This was duly provided on 17 January 2020 in accordance with HPRA policy. The listing included the aforementioned report, and was provided together with a caveat statement. The caveat highlighted, among other matters, that listings are subject to change, and inclusion of a particular report on a listing does not necessarily mean that the medicine caused the observed effect.
- Subsequently, it was established that the **report was submitted in error to the HPRA, and that there was no evidence of an Irish fatality having occurred.** The HPRA's national database is being updated accordingly, and follow-up with the member of the public to whom the listing was provided is underway.

Ongoing monitoring of vaccines is of utmost importance to public health. The HPRA takes its obligations in this regard very seriously, with the public interest in mind at all times. The HPRA fully supports transparency with the public. It is in this regard that listings of Irish reports are provided on request, and that we make additional information regarding the HPV vaccines available on the HPRA website (www.hpra.ie/homepage/medicines/special-topics/hpv-school-immunisation).

Information regarding suspected side effects for all vaccines and medicines is available to the public via the European Database for Suspected Adverse Reaction Reports (www.adrreports.eu). This website was launched in 2012 to provide public access to reports and is additional to availability of product information and the conclusions of safety reviews by the EMA's Pharmacovigilance Risk Assessment Committee (PRAC), at which the HPRA actively participates.

The benefit-risk profile of Gardasil and HPV vaccines remains positive.

Date: 24 January 2020

An tÚdarás Rialála Táirgí Sláinte, Teach Kevin O'Malley, Ionad Phort an Iarla, Ardán Phort an Iarla, Baile Átha Cliath 2, Éire
Health Products Regulatory Authority, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland
T: +353 1 676 4971 • F: +353 1 676 7836 • info@hpra.ie • **www.hpra.ie**