



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

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19th. November 2019

Deputy Michael Healy-Rae
TD
Dail Eireann
Kildare Street
Dublin 2

PQ Number 45905/19: To ask the Minister for Health if it will be clarified to parents that are signing consent forms for children that are receiving the HPV vaccine gardasil 9 that it is a black triangle medical product; and if he will make a statement on the matter.

Dear Deputy Healy-Rae,

The above PQ has been sent directly to my office for direct response to you on same.

Only licensed vaccines are purchased by the HSE for the School vaccination programme or primary immunisation programmes. The licence for Gardasil 9 was granted by the European Medicines Agency (EMA) who also monitors all reported suspected adverse reactions. The black triangle symbol does not mean that the medicine is unsafe; rather, it indicates that the medicine is new to the market and is being closely monitored by the regulatory network.

Gardasil 9 currently has a black triangle but there is no requirement for parents to be specifically informed about this because the teams administering the vaccine are advised to report all suspected adverse reactions to the HPRA and this is in line with the black triangle monitoring of Gardasil 9.

I hope this information will be of assistance to you.

Yours sincerely,

DR. KEVIN KELLEHER, FFPHM, FFPHMI
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