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Public statement

Silgard

Withdrawal of the marketing authorisation in the European Union

On 18 February 2019, the European Commission withdrew the marketing authorisation for Silgard (human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed)) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Merck Sharp & Dohme Limited, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Silgard was granted marketing authorisation in the EU on 19 September 2006 for prevention of diseases caused by specific human papillomavirus (HPV) types: cervical and anal cancer, precancerous or dysplastic lesions in the anus and female genitals, and genital warts. The marketing authorisation was initially valid for a 5-year period. It was then granted unlimited validity in 2011.

Silgard was a duplicate application to Gardasil, which is marketed in several EU countries. The marketing authorisation holder will maintain the marketing authorisation for Gardasil and Gardasil 9.

The European Public Assessment Report (EPAR) for Silgard will be updated to reflect that the marketing authorisation is no longer valid.

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