

SUPPLEMENTARY TABLE 1. WORLD HEALTH AUTHORITY AND GOVERNMENTAL STATEMENTS.

Organization	Date	Communication	Reference
WHO	24 October 2014	<p>The Global Advisory Committee on Vaccine Safety (GACVS); an update position paper on vaccines against diseases caused by human papillomaviruses This document replaces the first WHO position paper (HPV) published in 2009. It concludes that HPV vaccines have excellent safety and efficacy profiles.</p> <p>Their position is- Adverse events following HPV vaccination are generally non-serious and of short duration. The vaccines can be used in persons who are immune-compromised and/or HIV-infected. Vaccines should be avoided in pregnant women. Breastfeeding is not a contraindication for HPV vaccination.</p>	<p><a href="http://www.who.int/wer/2014/wer8943.pdf?ua=1">http://www.who.int/wer/2014/wer8943.pdf?ua=1</a></p>
	12 March 2014	<p>The Global Advisory Committee on Vaccine Safety (GACVS) continues to closely monitor the safety of HPV vaccines and, based on a careful examination of the available evidence, continues to affirm that its benefit-risk profile remains favorable. To date, there is no scientific evidence that aluminum-containing vaccines cause harm, that the presence of aluminum at the injection site (the MMF “tattoo”) is related to any autoimmune syndrome, and that HPV DNA fragments are responsible for inflammation, cerebral vasculitis, or other immune-mediated phenomena.</p>	<p><a href="http://www.who.int/vaccine_safety/committee/topics/hpv/GACVS_Statement_HP12_Mar_2014.pdf?ua=1">http://www.who.int/vaccine_safety/committee/topics/hpv/GACVS_Statement_HP12_Mar_2014.pdf?ua=1</a></p>
	14 February 2014	<p>The Global Advisory Committee on Vaccine Safety (GACVS) reviewed evidence related to autoimmune disease and the HPV vaccines, with a focus on multiple sclerosis (MS). “The Committee continued to be reassured by the safety profile of the available products. Serious adverse events that have been reported as potential signals have been investigated in more detail and were not confirmed, including Guillain-Barré syndrome, seizures, stroke, venous thromboembolism, anaphylaxis, and other allergic reactions. Surveillance of pregnancy outcomes among women inadvertently vaccinated during pregnancy through spontaneous reports and registries has not detected any adverse outcomes above expected</p>	<p><a href="http://www.who.int/wer/2014/wer8907.pdf">http://www.who.int/wer/2014/wer8907.pdf</a></p>

		rates.”	
17 December 2013		The Global Advisory Committee on Vaccine Safety (GACVS) was presented with a series of cases of adverse events following the HPV vaccine. Multiple studies have demonstrated no increase in risk of autoimmune diseases, including MS, among girls who received HPV vaccine compared to those who had not. The Committee continues to be reassured by the safety profile of the vaccine, but notes the importance of continued surveillance and epidemiological investigation with an emphasis on the collection of high quality data; such data are essential for interpreting adverse events which occur following vaccination. Allegations of harm from vaccination based on incomplete information can lead to real harm when, as a result, effective vaccines are not used.	<a href="http://www.who.int/vaccine_safety/committee/topics/hpv/GACVS_Dec_2013 HPV France Dec20_Final.pdf">http://www.who.int/vaccine_safety/committee/topics/hpv/GACVS_Dec_2013 HPV France Dec20_Final.pdf</a>
13 June 2013		The Global Advisory Committee on Vaccine Safety (GACVS) reviewed the safety profile of human papillomavirus vaccines and concluded that the Committee continues to be reassured by the safety profile of the available products.	<a href="http://www.who.int/vaccine_safety/committee/topics/hpv/130619HPV_VaccineGACVSstatement.pdf">http://www.who.int/vaccine_safety/committee/topics/hpv/130619HPV_VaccineGACVSstatement.pdf</a>
30 January 2009		The Global Advisory Committee on Vaccine Safety (GACVS) reviewed the safety profile of human papillomavirus vaccines which did not raise sufficient concern to change previous advice given by GACVS for HPV vaccination.	<a href="http://www.who.int/wer/2009/wer8405.pdf">http://www.who.int/wer/2009/wer8405.pdf</a>
9 January 2009		The Strategic Advisory Group of Experts (SAGE) on immunization recognized the importance of cervical cancer and other HPV-related diseases and recommended that HPV vaccination should be included in national immunization programs provided that prevention of cervical cancer and/or other HPV-related diseases constitutes a public health priority (i.e. to reduce disease burden and/or health care costs), vaccine introduction is programmatically feasible, sustainable financing can be secured and the cost-effectiveness of vaccination strategies in the country or region be considered.	<a href="http://www.who.int/wer/2009/wer8401_02.pdf">http://www.who.int/wer/2009/wer8401_02.pdf</a>
20 July 2007		At the request of the Strategic Advisory Group of Experts on immunization (SAGE), the Global Advisory Committee on Vaccine Safety (GACVS) reviewed the safety of human papillomavirus	<a href="http://www.who.int/wer/2007/wer8228_29.pdf">http://www.who.int/wer/2007/wer8228_29.pdf</a>

		(HPV) vaccines. No concerns with the safety profile were identified.	
CDC	July 2014	From June 2006 through March 2014, approximately 67 million doses of HPV4 were distributed in the United States. 92.4% of the HPV4 reports were classified as nonserious. Overall, reporting of adverse events to VAERS is consistent with prelicensure clinical trial data and consistent with the 2009 published summary of the first 2.5 years of postlicensure reporting to VAERS.	<a href="http://www.cdc.gov/vaccinesafety/Vaccines/HPV/Index.html">http://www.cdc.gov/vaccinesafety/Vaccines/HPV/Index.html</a> <a href="http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6329a3.htm?s_cid=mm6329a3_w">http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6329a3.htm?s_cid=mm6329a3_w</a>
	1 July 2013	Three population-based published studies of HPV4 vaccine safety, including one from CDC's Vaccine Safety Datalink, have been conducted in the United States. Although one post-licensure observational study found an increased risk for syncope, no serious safety concerns have been identified in these large post-licensure observational studies.	<a href="http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6229a4.html">http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6229a4.html</a>
	24 October 2011	To date, adverse events reported to VAERS are consistent with those identified during the vaccine's pre-licensure clinical trials, and reporting patterns have remained unchanged, with no new concerns, since a summary of VAERS reports was published in 2009.	<a href="http://www.cdc.gov/vaccinesafety/Vaccines/HPV/Index.html">http://www.cdc.gov/vaccinesafety/Vaccines/HPV/Index.html</a>
	23 December 2011	Recommendations on the Use of Quadrivalent Human Papillomavirus Vaccine in Males — Advisory Committee on Immunization Practices (ACIP), 2011.	<a href="http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6050a3.html">http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6050a3.html</a>
	28 May 28 2010	FDA Licensure of Quadrivalent Human Papillomavirus Vaccine (HPV4, Gardasil) for Use in Males and Guidance from the Advisory Committee on Immunization Practices (ACIP)	<a href="http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5920a5.html">http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5920a5.html</a>
	23 March 2007	These recommendations represent the first statement by the Advisory Committee on Immunization Practices (ACIP) on the use of the HPV4 vaccine licensed by the U.S. Food and Drug Administration on June 8, 2006.	<a href="http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5602a1.html">http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5602a1.html</a>
	29 August 2014	Human Papillomavirus Vaccination Recommendations This report summarizes the epidemiology of HPV and associated	<a href="http://www.cdc.gov/mmwr/pdf/rr/rr6305.pdf">http://www.cdc.gov/mmwr/pdf/rr/rr6305.pdf</a>

ACIP		diseases, describes the licensed HPV vaccines, <u>provides updated information on vaccines</u> from clinical trials and postlicensure safety studies and monitoring, and compiles recommendations from CDC's Advisory Committee on Immunization Practices (ACIP) for use of HPV vaccines. ACIP recommends routine vaccination at age 11 or 12 years with HPV4 or HPV2 for females and with HPV4 for males. ACIP also Vaccination also is recommended for females aged 13 through 26 years and for males aged 13 through 21 years. Males aged 22 through 26 years may be vaccinated.	
FDA	20 August 2009	Based on the review of available information by FDA and CDC, HPV4 vaccine continues to be safe and effective, and its benefits continue to outweigh its risks.	<a href="http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/ucm179549.htm">http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/ucm179549.htm</a>
	21 October 2011	The presence of DNA fragments is expected in HPV4 vaccine and not evidence of contamination. Based on the scientific information available to FDA, HPV4 vaccine continues to be safe and effective, and its benefits continue to outweigh its risks.	<a href="http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm276859.html">http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm276859.html</a>
ECDC	September 2012	The HPV vaccines currently in use for girls are generally safe, well tolerated and highly efficacious in the prevention of persistent infection, cervical cancer and cancerous and precancerous lesions related to the vaccine-HPV serotypes. The vaccines also confer some degree of cross-protection against non-vaccine-HPV serotype infection and precancerous cervical lesions.	<a href="http://www.ecdc.europa.eu/en/publications/publications/20120905_gui_hpv_vaccine_update.pdf">http://www.ecdc.europa.eu/en/publications/publications/20120905_gui_hpv_vaccine_update.pdf</a>
EMA	23 September 2011	European Medicines Agency's <a href="#">Committee for Medicinal Products for Human Use</a> (CHMP) has addressed concerns over the safety of the HPV4 vaccine and concluded that the HPV4 vaccine remains safe and effective.	<a href="http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2011/09/news_detail_001350.jsp&amp;mid=WC0b01ac058004d5c1">http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2011/09/news_detail_001350.jsp&amp;mid=WC0b01ac058004d5c1</a>
	19 February 2009	Based on the current data, the Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the cases (cases of convulsion in Spain) are unlikely to be related to vaccination with the HPV4 vaccine 1 and that the benefits of the HPV4 vaccine	<a href="http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2009/11/WC500011828.pdf">http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2009/11/WC500011828.pdf</a>

		continue to outweigh its risks.	
	24 January 2008	EMA statement on the safety of HPV4 vaccine and more specifically on the 2 death reports in EU. No causal relationship has been established between the deaths of the young women and the administration of the HPV4 vaccine. On the basis of the currently available evidence, the EMA's Committee for Medicinal Products for Human Use (CHMP) is of the opinion that the benefits of the HPV4 vaccine continue to outweigh its risks and that no changes to its product information are necessary.	<a href="http://www.emea.europa.eu/docs/en_GB/document_library/Press_release/2009/11/WC500015448.pdf">http://www.emea.europa.eu/docs/en_GB/document_library/Press_release/2009/11/WC500015448.pdf</a>
Flemish Agency for Care and Health (Belgium)	November 2013	A comment from Flemish Tendering authorities stating that they have full confidence in HPV vaccination and the added value in the prevention of cervical cancer	<a href="http://www.zorg-en-gezondheid.be/Nieuws/HPV-vaccin-Gardasil-is-veilig">http://www.zorg-en-gezondheid.be/Nieuws/HPV-vaccin-Gardasil-is-veilig</a>
	December 2014	Danish Pharmacovigilance Update The Danish Health and Medicines Authority still assesses that the benefits of the HPV vaccine outweigh the possible risks	<a href="http://sundhedsstyrelsen.dk/en/news/2014/~/_/media/3257BA9BB4FB40609CC7878437247B34.ashx">http://sundhedsstyrelsen.dk/en/news/2014/~/_/media/3257BA9BB4FB40609CC7878437247B34.ashx</a>
	1 May 2014	Danish Pharmacovigilance Update ADR reports involving the HPV vaccine received from 2009 to 31 March 2014. The overall conclusion of the HPV vaccine is still that the benefits outweigh the possible risks.	<a href="http://sundhedsstyrelsen.dk/en/news/2014/~/_/media/6843B419214D4E82A5A966808D71D73C.ashx">http://sundhedsstyrelsen.dk/en/news/2014/~/_/media/6843B419214D4E82A5A966808D71D73C.ashx</a>
Danish Health Authorities	1 January 2014	Danish Pharmacovigilance Update ADR reports from the HPV vaccine reported during the period 10 September through 30 November 2013. According to the DHMA's assessment the vaccine serves its purpose by being an essential element in the prevention of cervical cancer.	<a href="http://sundhedsstyrelsen.dk/en/news/2014/~/_/media/0540230C7344D6589018F88BB171F51.ashx">http://sundhedsstyrelsen.dk/en/news/2014/~/_/media/0540230C7344D6589018F88BB171F51.ashx</a>

20 June 2010	The Danish Medicines Agency's annual pharmacovigilance report 2010. In 2010, there were considerably fewer reports compared to 2009. In particular reports on atopic dermatitis, which were subject to much attention in 2009, dropped significantly in 2010. Primarily well-known non-serious side effects were reported for HPV4 vaccine in 2010, such as local reactions at the injection site, headache, fever, and nausea.	<a href="http://sundhedsstyrelsen.dk/en/news/2011/~media/BAC4DA2950FF4AE1BC6D559EC35AFB3B.ashx?m=.pdf">http://sundhedsstyrelsen.dk/en/news/2011/~media/BAC4DA2950FF4AE1BC6D559EC35AFB3B.ashx?m=.pdf</a>
23 February 2010	Adverse reactions from HPV4 vaccine between September 1 and December 31, 2009. In this period, the Danish Medicines Agency received 22 adverse reaction reports with a total of 52 suspected side effects from HPV4 vaccine. The majority of the adverse reaction reports are not serious and describe already known adverse reactions.	<a href="https://sundhedsstyrelsen.dk/en/news/2010/adverse-reactions-from-gardasil-in-the-period-1-september-31-december-2009">https://sundhedsstyrelsen.dk/en/news/2010/adverse-reactions-from-gardasil-in-the-period-1-september-31-december-2009</a>
24 July 2009	Adverse reactions from HPV4 vaccine between January 1 and April 30, 2009. In this period, the Danish Medicines Agency received 191 adverse reaction reports describing 280 adverse reactions. Only nine of these reports were classified as serious.	<a href="http://laegemiddelstyrelsen.dk/en/topics/side-effects-and-trials/side-effects/news/adverse-reactions-from-gardasil-in-the-p--pril-2009">http://laegemiddelstyrelsen.dk/en/topics/side-effects-and-trials/side-effects/news/adverse-reactions-from-gardasil-in-the-p--pril-2009</a>
10 April 2014	Update on Gardasil in France. The benefit/risk ratio of this vaccine, in view of all the data of efficacy and safety remains favorable. The ANSM continues the reinforced surveillance of Gardasil.	<a href="http://ansm.sante.fr/S-informer/Points-d-information-Points-d-information/Gardasil-actualisation-des-donnees-de-securite-sur-le-vaccin-contre-les-papillomavirus-humains-Point-d-information">http://ansm.sante.fr/S-informer/Points-d-information-Points-d-information/Gardasil-actualisation-des-donnees-de-securite-sur-le-vaccin-contre-les-papillomavirus-humains-Point-d-information</a>

ANSM (French Health Authority formerly known as AFSSAPS)	26 November 2013	Update on Gardasil in France. The benefit/risk ratio of this vaccine, in view of all the data of efficacy and safety remains favorable.	<a href="http://ansm.sante.fr/S-informer/Points-d-information-Points-d-information/Gardasil-vaccination-contre-les-papillomavirus-humains-HPV-Point-d-information">http://ansm.sante.fr/S-informer/Points-d-information-Points-d-information/Gardasil-vaccination-contre-les-papillomavirus-humains-HPV-Point-d-information</a>
	26 November 2013	Q&A on Gardasil in France. The international and French literature data do not show any increase in the incidence of autoimmune diseases or more specifically MS after a vaccination with Gardasil. The data from the French National Health Insurance, covering a cohort of near 2 million young girls born between 1992 and 1996 and followed-up through a period from 2008 to 2010 confirm these results.	<a href="http://ansm.sante.fr/S-informer/Points-d-information-Points-d-information/Gardasil-vaccination-contre-les-papillomavirus-humains-HPV-Point-d-information">http://ansm.sante.fr/S-informer/Points-d-information-Points-d-information/Gardasil-vaccination-contre-les-papillomavirus-humains-HPV-Point-d-information</a>
	1 December 2011	Update on HPV vaccines safety data in France.	<a href="http://ansm.sante.fr/Activites/Surveillance-des-vaccins/Vaccins-contre-les-infections-dues-a-certains-papillomavirus-humains-HPV/(offset)/1">http://ansm.sante.fr/Activites/Surveillance-des-vaccins/Vaccins-contre-les-infections-dues-a-certains-papillomavirus-humains-HPV/(offset)/1</a>
	1 July 2011	Third assessment of the European and national risk management plan.	<a href="http://www.ansm.sante.fr/var/ansm_site/storage/original/application/dd74df4740c453f1889d56ef5ddf4387.pdf">http://www.ansm.sante.fr/var/ansm_site/storage/original/application/dd74df4740c453f1889d56ef5ddf4387.pdf</a>
	30 September 2009	Second assessment of the European and national risk management plan.	<a href="http://www.ansm.sante.fr/S-informer/Presse-Communiqués-Points-presse/Gardasil-R-Second-bilan-du-plan-de-gestion-des-risques-europeen-et-national-Communique/(language)/fre-FR">http://www.ansm.sante.fr/S-informer/Presse-Communiqués-Points-presse/Gardasil-R-Second-bilan-du-plan-de-gestion-des-risques-europeen-et-national-Communique/(language)/fre-FR</a>
	15 July 2008	AFSSAPS presents the first pharmacovigilance report on Gardasil. Gardasil benefits continue to outweigh its risks.	<a href="http://www.ansm.sante.fr/S-informer/Presse-">http://www.ansm.sante.fr/S-informer/Presse-</a>

			<a href="#">Communiqués-Points- presse/Gardasil-R-premier- bilan-de-la-surveillance-des- risques-en-France- Communique</a>
Haut Conseil de la santé publique (HCSP, France)	10 September 2014	Pharmacovigilance data , international and national , with an experience of more than seven years, does not enable the selection of the existence of a causal link between vaccination and serious adverse events that were attributed to it [the vaccine] in France.	<a href="http://www.hcsp.fr/explore.cgi/avisrapportsdomaine?clefr=231">http://www.hcsp.fr/explore.cgi/ avisrapportsdomaine?clefr=231</a>
	22 November 2011	There is currently no data that may question the efficacy of these vaccines or suggest a potentially harmful nature of the vaccine in certain categories of the population , especially risk of developing cancer in women previously infected .	<a href="http://www.hcsp.fr/explore.cgi/avisrapportsdomaine?clefr=231">http://www.hcsp.fr/explore.cgi/ avisrapportsdomaine?clefr=231</a>
Agency of the German Federal Ministry of Health	13 February 2009	The Paul-Ehrlich-Institut comments on the cases of convulsion in Spain.	<a href="http://www.pei.de/DE/arzneimittelsicherheit-vigilanz/archiv-sicherheitsinformationen/2009/ablage/2009-02-12-hpv-spanien-info.html?nn=3256582">http://www.pei.de/DE/arzneimi ttelsicherheit-vigilanz/archiv- sicherheitsinformationen/2009/ ablage/2009-02-12-hpv- spanien-info.html?nn=3256582</a>
German government	28 May 2008	Detailed response from the German government to questions raised by the Green party. This response includes information on the HPV4 vaccine's safety profile.	<a href="http://dipbt.bundestag.de/dip21/btd/16/093/1609302.pdf">http://dipbt.bundestag.de/dip21 /btd/16/093/1609302.pdf</a>
Agenzia Italiana del Farmaco (AIFA)	2012	AIFA, National report about surveillance of postmarketing authorization of vaccines in Italy 2009-2012	<a href="http://www.agenziafarmaco.gov.it/">http://www.agenziafarmaco.go v.it/</a>
	2011	AIFA, National report about surveillance of postmarketing authorization of vaccines in Italy 2009-2011	<a href="http://www.agenziafarmaco.gov.it/">http://www.agenziafarmaco.go v.it/</a>
	2010	AIFA, National report about surveillance of postmarketing authorization of vaccines in Italy 2009-2010, States there is an active surveillance on adverse events of HPV vaccines, and both show to be in line with the SmPC	<a href="http://www.agenziafarmaco.gov.it/">http://www.agenziafarmaco.go v.it/</a>



	2008	Update on safety by 2008. No new signal of alert concerning HPV vaccines has been identified by the analysis of Italian data.	<a href="http://www.agenziafarmaco.gov.it/">http://www.agenziafarmaco.gov.it/</a>
	2007	Summary on HPV safety that states vaccines are safe.	<a href="http://www.agenziafarmaco.gov.it/">http://www.agenziafarmaco.gov.it/</a>
Irish Medicines Board	19 July 2011	Overview of National Monitoring Experience with Gardasil	<a href="http://www.imb.ie/images/uploaded/documents/IMB_Gardasil_WebUpdate_19Jul2011.pdf">http://www.imb.ie/images/uploaded/documents/IMB_Gardasil_WebUpdate_19Jul2011.pdf</a>
	20 May 2010	Drug Safety Newsletter - 37th Edition INSERT – Human papillomavirus (HPV) Immunisation Programme	<a href="http://www.imb.ie/images/uploaded/documents/Gardasil_Insert_May_200510.pdf">http://www.imb.ie/images/uploaded/documents/Gardasil_Insert_May_200510.pdf</a>
The Norwegian Medicines Agency	31 July 2014	<p>Conclusion: The reported adverse reactions are as expected and give no reason to change the current recommendations on the use of the vaccine. The HA continues to closely monitor the adverse event reporting of Gardasil</p> <p>The conclusion is based on the reported AE reactions since the introduction of the HPV immunization program in 2009</p>	<a href="http://www.legemiddelverket.no/Nyheter/Bivirkninger/Sider/Bivirkninger-av-HPV-vaksine--oppdaterte-tall-per-31.-august-2014.aspx">http://www.legemiddelverket.no/Nyheter/Bivirkninger/Sider/Bivirkninger-av-HPV-vaksine--oppdaterte-tall-per-31.-august-2014.aspx</a>
	31 December 2014	Conclusion: Reported side effects are as far as expected and give no reason to change the current recommendations for use of the vaccine.	<a href="http://www.legemiddelverket.no/Bivirkninger/bivirkningsnyheter/Documents/HPV%20januar%202015.pdf">http://www.legemiddelverket.no/Bivirkninger/bivirkningsnyheter/Documents/HPV%20januar%202015.pdf</a>
The Norwegian Institute of Public	16 February 2012	An annual report of HPV vaccine in the childhood vaccination program in 2011. Reported side effects so far are as expected, and gives no reason to change current recommendations about the use of the vaccine.	<a href="http://www.fhi.no/dokumenter/7ff40bd3b6.pdf">http://www.fhi.no/dokumenter/7ff40bd3b6.pdf</a>

Health			
Spanish Medicine Agency	23 April 2009	Press release - conclusions of the expert committee – Cases of convulsion in Spain.	<a href="http://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/seguridad/2009/docs/NI_2009-06_segVacuPapilomaHumano.pdf">http://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/seguridad/2009/docs/NI_2009-06_segVacuPapilomaHumano.pdf</a>
	6 April 2009	The AEMPS concludes that the risk-benefit ratio of vaccines against HPV has not undergone change and remains favorable.	<a href="http://www.msssi.gob.es/biblioPublic/publicaciones/recursos propios/infMedic/docs/vol33_2_InfSegurMedicamentos.pdf">http://www.msssi.gob.es/biblioPublic/publicaciones/recursos propios/infMedic/docs/vol33_2_InfSegurMedicamentos.pdf</a>
Swedish Medical Products Agency	8 May 2014	Based on available information, the vaccines in the national vaccination program continue to have a positive benefit/risk ratio.	<a href="http://www.lakemedelsverket.se/upload/nyheter/2014/Lakemedelssakerhet-2013.pdf">http://www.lakemedelsverket.se/upload/nyheter/2014/Lakemedelssakerhet-2013.pdf</a>
BAG (Swiss Federal Office of Public Health)	11 October 2010	Pharmacovigilance of vaccination against HPV - review of 4 years after marketing authorization.	<a href="http://www.bag.admin.ch/dokumentation/publikationen/01435/07914/index.html?lang=fr">http://www.bag.admin.ch/dokumentation/publikationen/01435/07914/index.html?lang=fr</a>
SWISSME DIC (Swiss Health Authority)	30 October 2014	Gardasil continues to have a positive benefit/risk ratio	<a href="https://www.swissmedic.ch/marktueberwachung/00135/00157/02468/index.html?lang=fr">https://www.swissmedic.ch/marktueberwachung/00135/00157/02468/index.html?lang=fr</a> Vaccins contre les papillomavirus humains (HPV) – Swissmedic
	13 February 2009	Swissmedic and Federal Office of Public Health will clarify incidents in Gardasil vaccination in Spain (comment on the cases of convulsion in Spain).	<a href="https://www.swissmedic.ch/aktuell/00673/00688/01620/index.html?lang=de">https://www.swissmedic.ch/aktuell/00673/00688/01620/index.html?lang=de</a>
	04 March 2009	Gardasil vaccination - two incidents in Spain / sequence information	<a href="https://www.swissmedic.ch/akt">https://www.swissmedic.ch/akt</a>

		for connection of 13 February 2009. Batch is not to be recalled.	<a href="http://www.tga.gov.au/safety/alerts-medicine-gardasil-130516.htm">uell/00673/00688/01615/index.html?lang=de</a>
TGA	16 May 2013	The TGA published a safety update regarding the HPV4 vaccine on 24 June 2010. Since then, the TGA has continued to monitor the vaccine. In that time, the TGA has identified no new safety signals. As with other regulators around the world, the TGA continues to consider the HPV4 vaccine to be safe and effective.	<a href="http://www.tga.gov.au/safety/alerts-medicine-gardasil-130516.htm">http://www.tga.gov.au/safety/alerts-medicine-gardasil-130516.htm</a>
	24 June 2010	As of this date, more than 6 million doses of the HPV4 vaccine have been distributed in Australia. The overall number of suspected adverse events reported following HPV4 vaccine administration is very low, and consistent with other new vaccines and adverse event rates reported in other countries.	<a href="http://www.tga.gov.au/safety/alerts-medicine-gardasil-070624.htm">http://www.tga.gov.au/safety/alerts-medicine-gardasil-070624.htm</a>

ACIP = Advisory Committee on Immunization Practices; WHO = World Health Organization; CDC = Centers for Disease Control and Prevention; FDA = Food and Drug Administration; ECDC = European Center for Disease Prevention and Control; EMA = European Medicines Agency; ANSM = Agence Nationale de Sécurité du Médicament et des Produits de Santé; AFSSAPS = Agence française de sécurité sanitaire des produits de santé; BAG = Bundesamt für Gesundheit; SWISSMEDIC = Swiss Agency for Therapeutic Products; TGA = Therapeutic Goods Administration.