



Executive Summary

Gardasil: Key Metrics in Nine Major Markets	Pharmaceutical
2012 Market Sales	
US	\$1,073.7m
5 EU	\$273.0m
Japan	\$86.8m
Canada	\$52.4m
Australia	\$43.4m
Total	\$1,529.3m
Key Events (2012–2022)	Level of Impact
Inclusion of males in routine vaccination in Australia in 2013	↑ ↑
Inclusion of males in routine vaccination in Canada from 2013	↑ ↑
Suspension of HPV vaccine recommendations in Japan	111
2022 Market Sales	
US	\$60.8m
5 EU	\$47.6m
Japan	\$3.7m
Canada	\$5.3m
Australia	\$4.4m
Total	\$121.7m
Source: GlobalData. 5 EU: France, Germany, Italy, Spain, UK	

Sales for Gardasil in the Prophylactic Human PapillomaVirus (HPV) Vaccines Market

GlobalData estimates that the Gardasil generated approximately \$1,529.3 million in sales in 2012. Gardasil is expected to experience a decline over the next 10 years, with anticipated sales of over \$121.7 million by 2022. This represents a negative compound annual growth rate of 22.4%. GlobalData expects that some of the most important drivers of global market growth over the next decade will be:

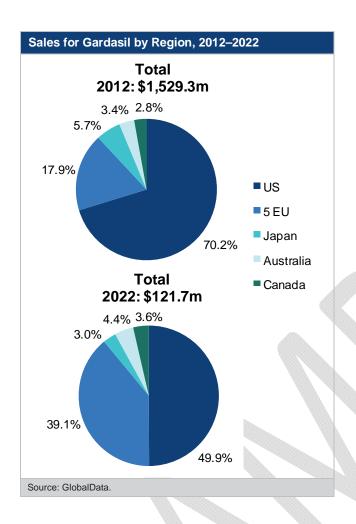
- Indicated for use in both males and females
- Provides protection against more HPV types than Cervarix

GlobalData believes that notable barriers to growth of the Gardasil will include:

- Long-term efficacy unknown
- Only protects against a limited number of HPV types



Executive Summary



What do the Physicians Think?

The KOLs interviewed for this report shared their expert insight into the HPV vaccines market. These KOLs acknowledged that significant barriers to HPV vaccine uptake exist, including fears over the safety of HPV vaccination, low awareness and the high price of the vaccines. KOLs welcomed the prospect of higher-valency vaccines, though they did warn that such vaccines should not be too expensive.

"HPV vaccination received very, very bad media attention in the beginning, it was questioned if it's useful, they said it is too expensive...it was said that it may be dangerous."

Key Opinion Leader, November 2013

"When I have done surveys and research on this [barriers to vaccination], it's all about safety."

Key Opinion Leader, November 2013

"What I feel is that the industry does not support this [increasing awareness of HPV vaccination], they do not give information... positive information, they are afraid to get again some controversy starting or criticism, so there is no source of information for the public."

Key Opinion Leader, November 2013

"We should try to get the price reduced because then the penetration of the market is much easier to do."

Key Opinion Leader, November2013

"We need bigger coverage, that's for sure."

Key Opinion Leader, November 2013

"Future vaccines covering more types [of HPV] will be really beneficial."

Key Opinion Leader, November 2013

"Adoption of nine-valent HPV vaccines depends on a number of factors, one of which I presume will be the price and impact on the federal budget."

Key Opinion Leader, November 2013



Table of Contents

1 Table of Contents

1	Tabl	le of Contents	4
	1.1	List of Tables	6
2	Intro	oduction	7
	2.1	Catalyst	7
	2.2	Related Reports	8
	2.3	Upcoming Related Reports	9
3	Dise	ease Overview	10
	3.1	Etiology and Pathophysiology	11
	3.1.1	Etiology	11
	3.1.2	Pathophysiology	11
	3.2	Symptoms	13
4	Vac	cination Recommendations and Coverage Rates	15
	4.1	Vaccination Recommendations Overview	15
5	Com	npetitive Assessment	17
	5.1	Overview	17
	5.2	Strategic Competitor Assessment	17
6	Gard	dasil	20
	6.1	Overview	20
	6.2	Efficacy	21
	6.3	Safety	23
	6.4	SWOT Analysis	24



Table of Contents

	6.5	Forecast	25
7	App	endix	26
	7.1	Bibliography	26
	7.2	Abbreviations	33
	7.3	Methodology	35
	7.4	Forecasting Methodology	35
	7.4.1	Vaccine Coverage	36
	7.4.2	Vaccine Approval versus Routine Schedule Inclusion	36
	7.4.3	General Pricing Assumptions	37
	7.4.4	Individual Drug Assumptions	38
	7.5	Physicians and Specialists Included in this Study	39
	7.6	About the Author(s)	42
	7.6.1	Author(s)	42
	7.6.2	Therapy Area Director	42
	7.6.3	Global Head of Healthcare	43
	7.7	About GlobalData	44
	7.8	Disclaimer	44



Table of Contents

1.1 List of Tables

Fable 1: Histological Progression Towards Cervical Cancer	.12
Fable 2: Diseases Associated with HPV Infection and Their Associated Symptoms	.14
Fable 3: HPV Vaccine Recommendation Agencies by Country	.16
Table 4: Targeted Group(s) for Recommended Immunization and Most-Administered HPV Vaccine by Count in the Global Markets, 2014	-
Table 5: Marketed Vaccines for HPV, 2014	.19
Fable 6: Product Profile – Gardasil	.21
Table 7: Phase III Efficacy Trials – Gardasil	.23
Fable 8: Safety Profile – Gardasil	.24
Fable 9: Gardasil SWOT Analysis, 2014	.24
Γable 10: Global Sales Forecasts (\$m) for Gardasil, 2012–2022	.25
Fable 11: High-Prescribing Physicians (non-KOLs) Surveyed, By Country	.41



Introduction

2 Introduction

2.1 Catalyst

The first prophylactic vaccine for immunization against human papillomavirus (HPV) became available in 2006. The global HPV vaccines market is now well established, yet vaccine coverage rates among the traditional target population of adolescent girls remain persistently low. Initially HPV vaccines were developed and marketed solely to protect against cervical cancer. In recent years the role of HPV in other cancers has been increasingly recognized, which has facilitated a shift towards vaccinating a wider population; most significant has been the inclusion of males in routine vaccine recommendations in some countries. The current HPV vaccines market is dominated by one major player, Merck's Gardasil, with GlaxoSmithKline's (GSK's) HPV vaccine Cervarix providing the only competition. However, the introduction of Merck's nine-valent vaccine is set to change the future landscape of the HPV vaccines sector.

The current HPV vaccines market is dominated by one major player, Merck's Gardasil, with GlaxoSmithKline's (GSK's) HPV vaccine Cervarix providing the only competition.

Below are some key factors affecting market growth over the forecast period:

- Globally HPV vaccine coverage rates have remained persistently low over recent years. There
 are a number of factors that contribute to these low coverage rates, including fears over
 vaccine safety and lack of awareness. Overcoming barriers to vaccination and increasing
 coverage rates would have a significant impact on the HPV vaccines market over the forecast
 period.
- There is increasing recognition of the benefits of vaccinating males against HPV. A number of countries have included males in recommendations for routine immunization, which will expand the patient population and drive growth in HPV vaccine sales in these countries.
- Following introduction of V503, GlobalData expects Merck's nine-valent vaccine to dominate the HPV vaccines sector. The introduction of this vaccine is likely to drive expansion in the size of the HPV vaccines sector over the forecast period.



Introduction

2.2 Related Reports

- GlobalData (2013). PharmaPoint: HIV Therapeutics Global Drug Forecast and Market Analysis to 2022: Event-Driven Update, March, 2013, GDHC41PIDR
- GlobalData (2013). PharmaFocus: Vaccine Adjuvants in Infectious Disease, March, 2013, GDHC001PFR
- GlobalData (2013). PharmaPoint: Pediatric Respiratory Syncytial Virus Prophylactics United States Drug Forecast and Market Analysis to 2022, April, 2013, GDHC102PIDR
- GlobalData (2013). PharmaPoint: HCV Therapeutics Global Drug Forecast and Market Analysis to 2022, May, 2013, GDHC42PIDR
- GlobalData (2013). PharmaPoint: Dermatophytic Onychomycosis United States Drug Forecast and Market Analysis to 2022, June, 2013, GDHC101PIDR
- GlobalData (2013). PharmaPoint: Meningococcal Vaccines Global Drug Forecast and Market Analysis to 2022, June 2013, GDHC51PIDR
- GlobalData (2013). PharmaFocus: Market Access Strategies for Antibiotics Targeting Multidrug-Resistant Gram-Negative Bacteria, August 2013, GDHC004PFR
- GlobalData (2013). PharmaFocus: HIV R&D Strategies Towards Cure and Prevention, August 2013, GDHC003PFR
- GlobalData (2013). PharmaPoint: Meningococcal Vaccines Global Drug Forecast and Market Analysis to 2022: Event-Driven Update, August 2013, GDHC61PIDR
- GlobalData (2013). PharmaPoint: Seasonal Influenza Vaccines Global Drug Forecast and Market Analysis to 2022: Event-Driven Update, September 2013, GDHC67PIDR
- GlobalData (2013). Prophylactic Hepatitis B Vaccines Global Drug Forecast and Market Analysis to 2022, January 2014, GDHC68PIDR
- GlobalData (2014). Prophylactic Human PapillomaVirus Vaccines Global Forecast and Market Analysis to 2022, March 2014, GDHC84PIDR
- GlobalData (2014). Prophylactic Human PapillomaVirus Vaccines US Drug Forecast and Market Analysis to 2022, March 2014, GDHC230CFR



Introduction

- GlobalData (2014). Prophylactic Human PapillomaVirus Vaccines 5 EU Drug Forecast and Market Analysis to 2022, March 2014, GDHC231CFR
- GlobalData (2014). Prophylactic Human PapillomaVirus Vaccines Japan Drug Forecast and Market Analysis to 2022, March 2014, GDHC232CFR
- GlobalData (2014). Prophylactic Human PapillomaVirus Vaccines Australia Drug Forecast and Market Analysis to 2022, March 2014, GDHC233CFR
- GlobalData (2014). Prophylactic Human PapillomaVirus Vaccines Canada Drug Forecast and Market Analysis to 2022, March 2014, GDHC234CFR
- GlobalData (2014). Prophylactic Human PapillomaVirus Vaccines Cervarix Forecast and Market Analysis to 2022, March 2014, GDHC387DFR
- GlobalData (2014). Prophylactic Human PapillomaVirus Vaccines V503 Forecast and Market Analysis to 2022, March 2014, GDHC388DFR
- GlobalData (2014). Prophylactic Human PapillomaVirus Vaccines Current and Future Players, March 2014, GDHC1032FPR

2.3 Upcoming Related Reports

 GlobalData (2013). Asthma Therapeutics – Global Drug Forecast and Market Analysis to 2022, April 2014, GDHC75PIDR



Appendix

7.7 About GlobalData

GlobalData is a leading global provider of business intelligence in the Healthcare industry. GlobalData provides its clients with up-to-date information and analysis on the latest developments in drug research, disease analysis, and clinical research and development. Our integrated business intelligence solutions include a range of interactive online databases, analytical tools, reports and forecasts. Our analysis is supported by a 24/7 client support and analyst team.

GlobalData has offices in New York, Boston, San Francisco, London, India and Singapore.

7.8 Disclaimer

All Rights Reserved.

No part of this publication may be reproduced, stored in a retrieval system or transmitted in any form by any means, electronic, mechanical, photocopying, recording or otherwise, without the prior permission of the publisher, GlobalData.

