PROPHYLACTIC HUMAN PAPILLOMAVIRUS VACCINES - CURRENT AND FUTURE PLAYERS
Human PapillomaVirus (HPV) Vaccine Sales Expected to Grow Modestly During the Forecast Period

GlobalData estimates that the global HPV vaccines market generated approximately $1.7 billion in sales in 2012. This market is expected to experience moderate growth over the next 10 years, with anticipated sales of over $2.2 billion by 2022. This represents a compound annual growth rate of 2.6%. HPV vaccine sales in Canada and Australia are expected to increase at a CAGR of over 9% during the forecast period, driven by the inclusion of males in routine HPV vaccine recommendations. The US is also expected to make a significant contribution to market growth, thanks to a large population and an estimated CAGR of 3%.

GlobalData expects that some of the most important drivers of global market growth over the next decade will be:

- Increasing inclusion of males in HPV vaccine recommendations
- Introduction of Merck’s nine-valent HPV vaccine, V503

GlobalData believes that notable barriers to growth of the global HPV vaccines market will include:

- Low HPV vaccine coverage rates among targeted populations
- Fears over the safety of HPV vaccines
- Low awareness of HPV and HPV vaccines among targeted populations
- Pressure on HPV vaccine programs to be cost-effective

Sales for HPV Vaccines by Region, 2012–2022

<table>
<thead>
<tr>
<th>Region</th>
<th>2012 Sales (in $bn)</th>
<th>2022 Sales (in $bn)</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>62.7%</td>
<td>62.7%</td>
</tr>
<tr>
<td>EU</td>
<td>23.8%</td>
<td>23.8%</td>
</tr>
<tr>
<td>Japan</td>
<td>7.9%</td>
<td>7.9%</td>
</tr>
<tr>
<td>Australia</td>
<td>2.6%</td>
<td>2.6%</td>
</tr>
<tr>
<td>Canada</td>
<td>3.1%</td>
<td>3.1%</td>
</tr>
</tbody>
</table>

Total: $1.7bn in 2012
Total: $2.2bn in 2022

Source: GlobalData.
Leading Players in the Global HPV Vaccines Market

The global prophylactic HPV vaccine market is presently dominated by Merck’s quadrivalent vaccine Gardasil; GSK’s bivalent vaccine Cervarix is the only other vaccine currently available for the prevention of HPV infection. Both vaccines have a similar mechanism of action, consisting of recombinant VLPs combined with an adjuvant, given as a three-dose course. The relative success of Gardasil over Cervarix has so far largely been driven by it being first to market and its ability to protect against the HPV types responsible for genital warts in addition to those responsible for the development of cervical cancer. Increasingly, Gardasil’s approval for use in males looks set to be an important factor driving its success, and this will continue to be a major factor influencing the future success of HPV vaccines.

The establishment of Gardasil as the market leader has allowed Merck to build a strong HPV vaccine franchise, and HPV vaccines now represent an important current and future revenue stream for Merck. In comparison, GSK’s Cervarix constitutes a relatively small part of the company’s vaccine portfolio. As well as manufacturing the market-leading vaccine, Merck has also aggressively pursued the development of a novel nine-valent HPV vaccine, V503, which has performed well in Phase III efficacy trials (Luxembourg, 2013). Merck’s V503 represents the only HPV vaccine currently in late-stage development. GlobalData therefore expects that Merck will remain the market leader throughout the forecast period, bolstered by its novel vaccine, which GlobalData estimates will achieve market approval in the US and Canada in 2015 and in the EU in 2016.

Company Portfolio Gap Analysis in HPV Vaccines, 2012–2022

Vaccines Protective against all HPV Types Represent Opportunity for New Players

The introduction of Merck’s nine-valent vaccine V503 will partially address the need to protect against more HPV types. Despite this, there will still be some remaining opportunity for new entrants into the HPV vaccines sector if they can demonstrate universal protection, against all HPV types. According to GlobalData’s primary research insight, such vaccines would be well received by...
physicians. A number of biotechnology companies are currently developing universal HPV vaccines; these vaccines utilize the minor capsid protein of HPV (L2), which is conserved across all HPV types. Such vaccines will need to induce a strong, durable immune response in order to replace traditional HPV vaccines.

**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, November 2013

“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
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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.

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). PharmaFocus: Vaccine Adjuvants in Infectious Disease, March, 2013, GDHC001PFR
- GlobalData (2013). PharmaPoint: Meningococcal Vaccines – Global Drug Forecast and Market Analysis to 2022, June 2013, GDHC51PIDR
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- GlobalData (2014). Prophylactic Human PapillomaVirus Vaccines – Cervarix Forecast and Market Analysis to 2022, March 2014, GDHC387DFR

2.3 Upcoming Related Reports

- GlobalData (2013). Asthma Therapeutics – Global Drug Forecast and Market Analysis to 2022, April 2014, GDHC75PIDR
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5.7 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.

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