Johnson & Johnson

Performance

Johnson & Johnson currently has relatively low vaccine revenues, reflecting its small portfolio size, volume of doses sold and geographic scope. However, its pipeline and R&D investments indicate a growing focus on vaccines. Overall, its performance is in the average range compared to other companies. It is a leader in Research & Development, making the largest investments in vaccine R&D and with a relatively large pipeline. In Pricing & Registration, it has filed to register vaccines in some low-income and lower-middle-income countries (LICs; LMICs). It has published only a very general commitment to affordable vaccine pricing. In Manufacturing & Supply, its performance is below average: while it has internal processes to align supply and demand, it is less active than peers in building manufacturing capacity, and has not implemented presentations or packaging to help overcome local access barriers for its two marketed vaccines.

Sales and Operations

Johnson & Johnson has three segments: consumer healthcare; pharmaceuticals; and medical devices. Its pharmaceuticals segment focuses on various therapeutic areas, including vaccines. Johnson & Johnson is present in 69 countries in scope. Sales in emerging and frontier markets account for 20% of total sales. Its vaccines are developed and produced by Janssen Vaccines & Prevention B.V. (part of Janssen Pharmaceutical Companies). Following the divestment of its oral typhoid and oral cholera vaccines, it now has two vaccines on the market.

Vaccine Portfolio

Johnson & Johnson has two vaccines on the market for five diseases in scope, one of the smallest portfolios of the companies evaluated. Its portfolio is made up of a single hepatitis B vaccine (Hepavax®) and a diphtheria, tetanus, whole-cell pertussis, hepatitis B and Hib combination vaccine (Quinvaxem®).

Opportunities

Commit to communicating supply discontinuation plans. Johnson & Johnson can commit to consistently communicating its intentions publicly when deciding to discontinue supply of a vaccine in future. This will allow stakeholders to adapt procurement and distribution plans early to minimise the risk of shortages and the potential impact on public health.

Consider barriers to access of marketed products. Johnson & Johnson can consider how its marketed products may present barriers to access in resource-limited settings, in terms of supply chain management, storage and administration. As it expands its R&D activities, it can adapt its existing vaccines, where possible, to address these barriers. Beyond vaccine development, it can adapt vaccine packaging and package inserts to address barriers to access.

Develop and publish a more specific pricing policy. Johnson & Johnson can outline how it defines the pricing tiers of its pricing policy, and include non-Gavi and non-PAHO country governments in its strategy, with a consideration of these countries’ ability to pay. By publishing a more specific pricing policy, which applies to new and existing vaccines, Johnson & Johnson can improve its accountability and ensure that self-financing countries have a better understanding of how to negotiate prices.
RESEARCH AREAS

RESEARCH & DEVELOPMENT

Largest R&D investments. Johnson & Johnson made the largest investments of companies evaluated in vaccine R&D targeting diseases in scope in 2014 and 2015, both in absolute terms (USD 717.3 mn) and as a proportion of its vaccine revenue (253%).

Relatively large vaccine pipeline. Johnson & Johnson has 14 R&D projects in its pipeline, targeting at least 13 diseases in scope. One of its projects targets a disease prioritised by WHO for vaccine R&D: its phase II HIV vaccine candidate.

Access provisions in place for three late-stage projects. Johnson & Johnson has at least one access provision in place for three out of its four late-stage projects. For example, it aims to register its Ebolavirus and HIV vaccine candidates in countries where clinical trials take place. These two vaccines are being trialled in six and four countries in scope respectively.

Vaccine pipeline

Johnson & Johnson has the largest number of projects in pre-clinical development.

<table>
<thead>
<tr>
<th>Discovery</th>
<th>Pre-clinical</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Technical lifecycle</th>
<th>Recent approvals</th>
</tr>
</thead>
<tbody>
<tr>
<td>HPV*</td>
<td>RSV (older adults)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>RSV (paediatric)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E. coli - 12-valent ExPEC</td>
<td>HIV</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Polio</td>
<td>E. coli - quadrivalent ExPEC</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S. aureus</td>
<td>DTPHibHep - (Quinvaxem®, multidose vial)**</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Confidential project</td>
<td>Ebolavirus - monovalent</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Confidential project</td>
<td>Viral hepatitis - B (Hepavax-Gene®, thermostability testing)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Since the period of analysis, this project has moved to pre-clinical development.
**Since the period of analysis, this project has moved to phase I development.
***Since the period of analysis, this project has been discontinued.

PRICING & REGISTRATION

General pricing strategy. Johnson & Johnson makes a broad commitment to using a tiered pricing approach for key vaccines in developing countries. However, it only provides UNICEF and PAHO as examples of procurers for whom it differentiates prices (based on countries’ wealth). It is not clear how the company takes affordability into account for non-Gavi, non-PAHO self-procuring countries. As part of its pricing strategy, the company states that vaccines specifically developed for poorer countries and not sold in affluent markets must stay profitable in order to sustain production, uphold quality and recoup investments.

Extends Gavi prices to Gavi-transitioning countries. In January 2015, Johnson & Johnson extended its pledge to make its pentavalent vaccine (Quinvaxem®) available at Gavi prices to transitioning countries over the next five years.

On-average performance in registration filing. Johnson & Johnson has filed to register both of its relevant vaccines in some LICs and some LMICs. Johnson & Johnson’s policy is to file for registration in countries where there is a medical need, taking into account regulatory and market hurdles.

On-average transparency. Like its peers, Johnson & Johnson does not systematically publish all prices for its vaccines in all countries in scope. Unlike leaders in this area, it only discloses a high-level version of its general pricing policy, with limited detail. Like most of its peers, it states that it does not include non-disclosure clauses regarding vaccine prices in its contracts with governments and other procurers.

MANUFACTURING & SUPPLY

Above average performance in aligning supply and demand. Johnson & Johnson has an above-average approach to ensuring sufficient vaccine supply. It makes a strong commitment to staying in vaccine markets where needed, and has a relatively comprehensive internal process for preventing and responding to shortages.

Some activity in building manufacturing capacity. Johnson & Johnson undertakes a relatively small number of activities to build vaccine manufacturing capacities in countries in scope. It provides operational and technology support to Vabiotech in Vietnam, a state-owned company producing vaccines for cholera, hepatitis A and B, and Japanese encephalitis.

Limited focus on vaccine presentations that support access. Johnson & Johnson’s performance is comparatively weak when it comes to ensuring its marketed products help to support access on the ground. It has adaptations in development, but has not yet implemented relevant presentations or packaging for marketed products.