Pricing & price transparency in pharmaceuticals: Pneumococcal conjugate vaccines

This briefing provides information to investors on pricing and price transparency of life-saving vaccines, specifically pneumococcal conjugate vaccines (PCV). A case is made for investors to engage with vaccine suppliers Pfizer and GlaxoSmithKline (GSK) in support of new and more transparent pricing policies.

Pneumonia is the single largest cause of death for children under five globally, and Pfizer and GSK currently hold a duopoly over the main vaccines – pneumococcal conjugate vaccines – to combat the disease. The two companies are increasingly under pressure from more than 50 countries in the World Health Assembly, international health charities, US presidential candidates and the world’s media, to reduce the high price of PCV vaccines, which is the primary reason why the cost of fully vaccinating a child is now 68 times more expensive than it was in 2001. To compound this global pressure, several competitors are poised to enter the PCV market with low-priced alternatives focusing investors’ attention on Pfizer and GSK’s pricing strategy.

The vaccine pricing landscape remains opaque, with prices paid for the same vaccine rumoured to vary significantly from one country to another. In 2015, Pfizer’s PCV vaccine, Prevnar 13 was the highest earning vaccine in the company’s portfolio, with sales surpassing US $6.25 billion. Despite these record sales in 2015, Prevnar 13 remains out of reach for many of those most affected by pneumonia, specifically children in the developing world, due to high pricing. Investors are invited to engage with Pfizer and GSK to request more transparent pricing, a reduction in the price of PCV vaccines and a guarantee that international humanitarian agencies have access to the lowest global price. These requests are essential to ensuring access to this life-saving vaccine, as PCV alone accounts for 45% of the cost of fully vaccinating a child in the least developed countries.

PCV related risks for investors in Pfizer and GSK

• Low-price competitors look set to enter the PCV market as soon as 2018.
• Aggressive pricing strategies look particularly vulnerable to regulatory action in the US but regulatory proposals are also forthcoming in the EU and G7.
• A World Health Assembly resolution on more affordable vaccines, including Pfizer and GSK’s PCV, passed unanimously in 2015.
• Vaccine pricing is attracting growing media scrutiny and attention by US presidential candidates and international health charities.

i | Calculation based on lowest global price.
The preventable death of children: The big price for Big Pharma

Pneumococcal disease, a bacterial infection that causes inflammation of the lungs, results in the death of almost one million children each year, mainly in developing countries. These deaths are preventable through vaccination, adequate nutrition and by addressing environmental factors. The most common cause of pneumonia is the pneumococcal bacterium, *Streptococcus pneumoniae*. In 2007, the World Health Organization (WHO) recommended that pneumococcal vaccines be introduced into all national immunisation programmes, particularly in countries with high child mortality. There are currently two WHO-endorsed PCV vaccines available on the market: Pfizer’s *Prevnar 13* (PCV13) and GSK’s *Synflorix* (PCV10). As of January 2016, although 129 countries have introduced PCV vaccine into their national immunisation schedules, more than 65% of children around the world remain unprotected from pneumococcal diseases. Many countries, including China, Thailand, and Malaysia currently do not immunise with PCV despite the vaccine being recommended as essential for children under five by the WHO. The entry into the PCV market of cheaper alternatives should increase coverage of children in untapped markets, and is liable to see Pfizer and GSK lose market share.

Even using the lowest subsidised prices, the cost of fully vaccinating a child, according to the WHO immunisation schedule, is now 68 times higher than it was just over a decade ago. Even using the lowest subsidised prices, the cost of fully vaccinating a child, according to the WHO immunisation schedule, is now 68 times higher than it was just over a decade ago.

Vaccine price data is scarce, but published prices for Pfizer’s *Prevnar 13* (PCV13) range from US $3.30/dose (Gavi) to US $116.91/dose (US CDC). At least three doses are required to fully protect a child against pneumonia and even at the lowest price it costs nearly US $10 per child.
from price-lowering competition. This situation is evolving, however, as several developing country manufacturers are getting closer to bringing lower cost alternatives to market.

Transparency: The road to recovery

Most pharmaceutical companies do not make vaccine prices public, and many require purchasers to sign confidentiality agreements which prohibit disclosure of price information. Despite governments and humanitarian organisations speaking out on the issue, Pfizer and GSK continue to refuse to reveal comprehensive price and cost information. Prior to the launch of the WHO Vaccine Product, Price and Procurement (V3P) project in 2011, there was no aggregate information source available for vaccine prices. As a result of this WHO project, some vaccine prices have now been added to a publicly-available database but information remains scarce, preventing effective negotiation between developing countries and pharmaceutical companies.

In a landmark milestone in May 2015, the 194 member states of the World Health Assembly unanimously adopted a resolution calling for increased price transparency and affordability of vaccines. The resolution stressed the current problems with procurement by middle income countries, and recommended more pooled procurement, publication of pricing, and local manufacturing where possible.

At present, the lowest income countries (<US $1,580 GNI per capita) have access to the lowest global price through Gavi, the Vaccine Alliance. A country’s Gross National Income (GNI) per capita is used as criteria for Gavi support (countries < GNI per capita of US $1,580 are eligible). Gavi support is meant to be temporary and countries’ co-financing of vaccines increases as their national income grows until they reach the $1,580 GNI per capita threshold. Once countries cross the eligibility threshold, Gavi support is phased out over a five-year period. More than one-third of eligible countries are currently losing support or ‘graduating’ from the programme. When these middle income countries lose Gavi support, they struggle to afford the vastly increased costs of immunisation, jeopardising the sustainability of their immunisation programmes.

Furthermore, most of the world’s poor children actually live in middle income countries (>US $1,580 - <US $8,500 GNI per capita) with a wide wealth disparity. While Gavi publishes the prices it negotiates for its eligible countries, price information for vaccines is not released for the majority of non-Gavi-eligible countries; indicative pricing shows that in some of these countries, vaccine prices can reach more than 20 times the Gavi prices, for example in Morocco the price was US $96.36 per dose in the retail market (30 times the Gavi price). As a result, governments and charitable health organisations are often negotiating in the dark, and some middle income countries are known to have paid more than developed countries for the same vaccine.

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Pfizer and GSK argue that price transparency would breach existing confidentiality agreements with state health authorities and have stated that they are making little to no profit with heavy discounts to Gavi. However, analysis commissioned by Gavi in 2013 after the launch of the pilot PCV programme, indicated that purchasers were at a severe disadvantage compared to the suppliers as they did not have insight into the true cost of manufacturing the vaccine and had to rely on incomplete and often out-of-date information in order to negotiate a price for their vaccination programmes. The analysis also found that even at a price of US $3.50/dose, the lowest price available during the study, the manufacturers were likely to be earning “returns greater than what was necessary to incentivize their participation in the Pilot”.

At the Gavi price, the study found that Pfizer would earn returns above 20% and that GSK would earn returns between 10 and 20% or above, incorporating

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ii | Created in 2000, Gavi, the Vaccine Alliance, brings together public and private sectors with the goal of creating equal access to vaccines for children living in the world’s poorest countries.

iii | A three year average GNI per capita above US $1,580.

iv | Based on World Bank data on GNI per capita based on purchasing power parity (PPP), and World Bank classification of lower/ lower middle/ upper middle income countries: [http://data.worldbank.org/indicator/NY.GNP.PCAP.PP.CD](http://data.worldbank.org/indicator/NY.GNP.PCAP.PP.CD)
the US $1.5 billion front-loaded subsidy to fund related capital costs for manufacturing, and assuming a US $3 manufacturers’ marginal cost of goods sold (COGS).  

This finding - that Gavi prices still leave pharmaceutical firms with a good margin over cost - was compounded by GSK’s recent statement at a press conference to announce the retirement of chief executive Sir Andrew Witty that the price charged to Gavi will be reduced from US $3.40/ dose to US $3.05/ dose, beginning in 2017. \(^{17}\) This welcome pricing concession for Gavi countries does not change the situation for children in middle income countries who do not have access to this price regime, nor for the more than 30% of Gavi countries soon to ‘graduate’ who face an unpredictable long-term pricing landscape.

Vital signs: Pfizer & GSK’s financial situation

Pfizer has made more than US $26 billion in sales from the pneumonia market since 2009 while GSK has made US $3.5 billion in the same period. Pfizer announced that sales of Prevnar 13 grew 102% in 2015, which helped lift the total revenue from Prevnar products to $6.25 billion. \(^{18}\) This increase was driven by a marketing push into G7 countries as well as a favourable committee recommendation by the US Centers for Disease Control and Prevention (CDC) for universal use in the growing 65-and-over age range. \(^{19}\)

Figure 2: Pfizer and GSK Revenue from PCV products 2010-2015

Source: Data obtained from GSK and Pfizer financial statements (2010-2015). GSK’s data converted using annual GBP/USD exchange rates.

GSK has switched its focus to vaccines and consumer healthcare to address concerns over dwindling revenues in other areas. \(^{20}\) Revenue from Synflorix actually declined slightly to US $583 million in 2015, driven by reportedly lower demand in Latin America. However, increased market access and demand in Africa and Bangladesh point to likely higher revenues in 2016.

Opportunities & risks: What investors need to know

Pfizer has a market capitalisation of US $183bn, whilst UK-based GSK is the third largest constituent of the FTSE100 with a market capitalisation of $104.3bn. \(^{21}\) As such, Pfizer and GSK holdings can be found in many US and UK pension fund and other institutional investment portfolios. If the vaccine pricing concerns highlighted in this briefing are not handled well, investors will continue to be exposed to a growing range of financial and non-financial risks. A number of these are highlighted below.

Competition

Several emerging market manufacturers are in the process of expanding production of vaccines including PCV. These include the Serum Institute of India (SII), Panacea and SK Chemicals (South Korea) in conjunction with Sanofi. These emerging market manufacturers are at various stages of obtaining approval but it is expected that the market for PCV could significantly open up as early as 2018.

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In response to the threat of competition from Indian and Korean manufacturers, Pfizer has attempted to patent a production method for PCV13. Pfizer’s response has met with strong opposition, with official pre-grant oppositions filed by both Panacea and MSF. \(^{22}\) A similar patent has already been
revoked by the European Patent Office (EPO). The Serum Institute of India has announced a dedicated manufacturing site for the PCV vaccine and a US $2/dose price, which would be significantly cheaper than the current Pfizer and GSK products. They have also secured an agreement to provide PCV to Russia, which may result in the loss of the contracts in Russia for Pfizer and GSK. The market for the pneumococcal vaccine in Russia is significant, with 1.7 million children eligible for vaccination. SII also has a venture with Indian drug manufacturer Cipla to seek regulatory approval to market SII’s paediatric vaccines in Europe.

It would appear there is a substantial untapped market in countries currently unwilling or unable to add PCV to their national immunisation programmes at current prices. Middle income countries with significant vaccine markets, such as China, Thailand, and Malaysia currently do not immunise with PCV despite it being recommended by WHO for routine immunisation. As has been the case with Russia which previously did not immunise with PCV, these large markets could be opened if pricing was made public and cost decreases applied.

Regulatory risk

In the US, more than 50 legislative proposals have responded to growing recognition of the public health challenges created by high drug prices. The proposals are wide ranging and arise from federal, state and other agencies. The White House fiscal year 2017 Budget Request to Congress contains a number of proposals to try to address high prices, stating that “the Administration is deeply concerned about rapidly growing prescription drug prices.”

Among other things, the Budget Request to Congress proposes to provide the Secretary of Health and Human Services with the authority to require drug manufacturers to publicly disclose information, including research and development costs, discounts, and other data as determined through regulation. It also includes three previously proposed reforms designed to increase access to generic drugs by stopping companies from entering into anti-competitive deals intended to block consumer access to safe and effective generics, by restricting brand manufacturers to seven years of exclusivity, rather than 12 years under current law, and by prohibiting additional periods of exclusivity for brands due to minor changes in product formulations.

In 2015, the US pharmaceutical firm Turing triggered public outrage when it increased the price of the drug Daraprim, used to fight life-threatening parasitic infection, from US $13.50 a tablet to US $750 overnight which resulted in treatment costs for some patients skyrocketing into the hundreds of thousands of dollars. When the Turing controversy erupted, US presidential candidate Hillary Clinton stated via Twitter, that she would limit the amount pharmaceutical companies could charge for their drugs should she get into office. This suggestion of regulatory change resulted in a fall in share prices within the healthcare industry. In New York, the Nasdaq Biotechnology Index fell 4.7 percent, the biggest intraday drop for that month.

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Corporate scandals, particularly related to pricing, have grown recently in the pharmaceutical sector, leading to high fines and sharp drops in share price. The latest pricing scandal to hit the pharmaceutical sector is Valeant Pharmaceuticals which experienced a 72.5% drop in share price in the six months to April 2016. The company is being investigated by the SEC and has been subpoenaed by district attorneys in Massachusetts and New York over its aggressive pricing strategies.

Pfizer has been implicated in controversies related to pricing for more than 50 years. In 2002, Pfizer paid US $49 million to settle charges that the company defrauded the US Medicaid programme by overcharging for its cholesterol-lowering drug Lipitor. In February, Pfizer agreed to a potential US $785m fraud settlement, to settle charges that its subsidiary Wyeth deliberately overcharged Medicaid for its acid reflux drug Protonix.

GSK has been fined by the Argentinian government for mismanagement of its trials for Synflorix in

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The role for investors

By engaging with pharmaceutical companies on PCV pricing, investors can help to ensure that lifesaving vaccines are available to children who need them across the world, whilst protecting and possibly growing global sales by the two firms that currently dominate the market.

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PFZW has indicated that companies that ignore its recommendations could expect the pension fund to divest its holdings.

Other institutional investors are increasingly focusing their attention on the sustainability of drug pricing and on what can be done to influence the situation via collaborative shareholder initiatives. The PRI Clearinghouse initiative on this topic has attracted the support of more than 50 institutional investors including several high street names in the fund management sector.

The focus of the SDGs on life-saving vaccines as a key driver of human development has also helped generate investor interest in this area. A growing number of institutional investors are exploring how their investments can align with and help to achieve the SDGs. More details on the SDGs can be found in Appendix 1.

Sustainable development

Access to safe, affordable vaccines has been enshrined in the Sustainable Development Goals (SDGs), which were ratified by 193 governments at the UN in September 2015. Since then, Secretary General Ban Ki Moon has convened a panel of former heads of state, leading international judges, civil society leaders, academics, and industry leaders to form the UN High-Level Panel on Access to Medicines. The Panel will report in June 2016 on how to harmonise international policies and present a holistic solution. Recently, French President Francois Hollande called for drug pricing to be included in the agenda at the G7 summit in Japan in May. It is expected that President Hollande will call for “greater cooperation between countries on drug pricing.”

The unanimous passing of the WHO resolution on vaccine pricing in 2015 as well as the numerous governments, US presidential candidates and other organisations speaking out on high vaccine prices, seems likely to guarantee sustained media attention on this issue, not only for companies but also, potentially, for their investors.

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Recommendations for investors

- Engage with Pfizer and GSK on PCV pricing, including through private meetings, company earning calls, at AGMs, and through both public and private collaborative shareholder initiatives.

Key questions include:

- Are you reviewing your business model for the PCV vaccine in light of the declining political and regulatory tolerance for current pricing strategies?
- Will you commit to fully transparent pricing of vaccines as recommended by the World Health Organization?
- Will you modify vaccine pricing to ensure that humanitarian organisations have access to the lowest global prices for life-saving vaccines?
- Will you consider pricing the PCV vaccine at US $5 per child in all developing countries?

Asset owners are encouraged to ask their asset managers to engage with pharmaceutical companies on disclosures around vaccine pricing and to support shareholder initiatives requesting that pharmaceutical companies manage access to medicine issues in developing countries (low and middle income countries).

For more information on MSF’s “A Fair Shot Campaign” visit http://www.afairshot.org/
Acknowledgement

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About MSF

Médecins Sans Frontières (MSF) / Doctors Without Borders (MSF) is an international, independent, medical humanitarian organisation that delivers emergency aid to people affected by armed conflict, epidemics, natural disasters and exclusion from healthcare.

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UN Sustainable Development Goals

On September 25th 2015, countries adopted a comprehensive set of goals to end poverty, protect the planet, and ensure prosperity for all as part of a new sustainable development agenda. Each goal has specific targets to be achieved over the next 15 years. The goals below relate specifically to access to vaccines.

United Nations Sustainable Development Goals

3.8 Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.

3.b Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all.

World Health Organization

The World Health Organization (WHO) has recommended that vaccine prices be public and transparent. In May 2015, the World Health Assembly (the decision-making body of WHO) passed resolution WHA68.6 to improve access to sustainable supplies of affordable vaccines – a key issue for Low and Middle Income Countries aiming to extend immunisation to the entire population.

WHA68.6 Global Vaccine Action Plan

URGES Member States:
1. to allocate adequate financial and human resources for the introduction of vaccines into national immunization schedules and for sustaining strong immunization programmes in accordance with national priorities;
2. to strengthen efforts, as and where appropriate, for pooling vaccine procurement volumes in regional and interregional or other groupings, as appropriate, that will increase affordability by leveraging economies of scale;
3. to provide, where possible and available, timely vaccine price data to WHO for publication, with the goal of increasing affordability through improved price transparency, particularly for new vaccines;
4. to seek opportunities for establishing national and regional vaccine manufacturing capacity, in accordance with national priorities, that can produce to national regulatory standards, including WHO-prequalification;
5. to create mechanisms to increase the availability of comparable information on government funding for vaccine development and work towards strategies that enhance public health benefit from government investments in vaccine development;
6. to support the ongoing efforts of various partners coordinated by WHO to design and implement the strategies to address the vaccine and immunization gaps faced by the low- and middle-income countries that request assistance;
7. to improve and sustain vaccine purchasing and delivery systems in order to promote the uninterrupted and affordable safe supply of all the necessary vaccines and their availability to all immunization service providers;
8. to strengthen immunization advocacy and provide training to health professionals and information to the public regarding immunization issues in order to achieve a clear understanding of the benefits and risks of immunization.