

## **Why GAVI Needs to Do More To Ensure Lower Vaccine Prices... ...And How It Could Be Done**

Vaccines are widely considered a highly cost-effective public health intervention. Médecins Sans Frontières (MSF) is actively involved in immunisation in many countries where we work, vaccinating millions of children every year. We strongly encourage increased support to immunisation activities.

However the recent introduction of new vaccines has raised considerably the price tag for immunisation. The Global Alliance for Vaccines and Immunisation (GAVI), the largest purchaser of vaccines for developing countries has failed to bring down vaccine prices to affordable levels. Part of the reason is conflict of interest within GAVI governance structures: major suppliers of vaccines to GAVI are also directly involved in setting policies for the organisation. As GAVI turns to donors to fill a US\$3.7 billion funding gap ahead of a June replenishment meeting, this briefing paper focuses on the problem of high vaccine prices, and outlines what donors should ask for in exchange for signing a cheque.

### **What is GAVI?**

The Global Alliance for Vaccines and Immunisation (GAVI) is the primary vehicle for financing the procurement of vaccines for low-income countries. GAVI also provides funding to countries for technical support and capacity-building assistance to strengthen health systems and immunisation activities. While GAVI currently provides support to 72 countries, this will be reduced to 56 countries by 2015.

### **Who funds GAVI?**

GAVI receives about 80% of donor government funding from seven countries: the UK, France, Italy, the US, Norway, Canada and the Netherlands.<sup>1</sup> Smaller contributions come from Australia, Denmark, the European Commission, Germany, Ireland, Luxembourg, Republic of Korea, Russia, South Africa, Spain, and Sweden. The Gates Foundation also contributes significantly, and will give the organisation over US\$1.5 billion from 2000-2014.

### **How has GAVI raised funds?**

In addition to general donor funds granted to GAVI to buy vaccines and support immunisation programmes, GAVI has set up the International Finance Facility for Immunisation (IFFIm) which has issued bonds on capital markets based on donor pledges.

## **I - Why current prices are a problem**

Prices paid by GAVI, by low- and middle-income countries, and by independent vaccine purchasers like MSF are too high, especially for newer vaccines like pentavalent (DTP+Hib+HepB), pneumococcal conjugate (PCV), and rotavirus.

**High vaccine prices mean fewer children can be vaccinated for the same amount of money.** The combination of relatively high prices and a lack of donor support forces GAVI to ration their support to countries. In 2010 countries were limited to introducing only one additional vaccine at a time. Multiple requests were not considered.

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<sup>1</sup> <http://www.nature.com/news/2010/100316/full/464338a.html>

**High GAVI prices also affect other actors, including MSF**

MSF is directly dependent on the prices that GAVI pays although it receives no funding from GAVI: GAVI has a much larger purchasing power for vaccines than MSF and it also ensures in its agreements with manufacturers that it receives the worldwide lowest prices. Low- and middle-income countries outside GAVI also face similar challenges when negotiating prices.

**The cost of vaccinating a child in the developing world has increased significantly** in the past decade as new vaccines have been introduced. In 2001, the cost of vaccinating a child in a developing country was at most US\$2.41 for a then-routine immunisation schedule (3 x DTP, 1 x BCG, 2 x measles, 3 x OPV).<sup>2</sup> Today, the minimum cost per child is US\$18.04 for a GAVI country that has replaced DTP with pentavalent and added PCV to their vaccine schedule. Adding rotavirus would increase this total cost per child to US\$33.04.<sup>3</sup> This cost may be substantially higher for non-GAVI countries that often pay more for the same new vaccines. Pentavalent, pneumococcal and rotavirus vaccines prevent diseases that cause hundreds of thousands of child deaths each year. These new vaccines are therefore welcome additions in developing countries. However, GAVI's focus on new vaccines and simultaneous failure to sufficiently bring down prices has serious consequences on the affordability of countries' vaccine schedules.

**Price is a ticking time-bomb for countries that will soon no longer be eligible for GAVI support.**

Once countries cross a per capita income threshold and "graduate" from GAVI, they will find it difficult to afford vaccines on their own. Honduras is a prime example: the country will graduate from all GAVI support in 2015, though its 2009 average per capita income was only \$1800. Under GAVI, it has introduced both rotavirus and PCV, and currently pays \$1.05 per child in co-financing for the two vaccines.<sup>4</sup> When GAVI support ends, provided prices stay the same, Honduras will pay \$25.50 per child for PCV and rotavirus vaccines, in addition to what it already pays for other routine immunisations. A Kenyan Ministry of Health official likened the introduction of new vaccines under GAVI to "taking out multiple mortgages."<sup>5</sup>

**High prices contribute to creating a funding crunch within GAVI.** The organisation faces a US\$3.7 billion shortfall to carry out activities until 2015. GAVI has compounded the problem of high prices by undertaking expensive innovative financing mechanisms that fail to represent value for donor money. The \$1.5 billion Advance Market Commitment (AMC) subsidy to vaccine producers is one example of GAVI's inability to negotiate affordable prices and subsequent overpayment for millions of vaccines. For more details on the AMC, see the box below on "The Advance Market Commitment".

GAVI hopes to raise funds to make up the \$3.7 billion shortfall at its replenishment meeting in London on 13 June 2011. While increased support for GAVI is critical, donors should require improved GAVI policies so GAVI can do more with the money it receives.

**The Advance Market Commitment: the perils of paying too much**

The Advance Market Commitment (AMC) was originally envisioned as an incentive for pharmaceutical companies to invest in R&D for vaccines needed in the developing world. But this mechanism has instead been used to fund increased production of existing pneumococcal vaccines

<sup>2</sup> Calculated using Unicef pricing data, available at: [http://www.unicef.org/supply/index\\_57476.html](http://www.unicef.org/supply/index_57476.html)

<sup>3</sup> Calculated using: GAVI PCV price of \$10.50 (3 x \$3.50/dose), Unicef pricing data for 2010 (1 x BCG, 2 x measles, 3 x OPV, 3 x DTP+HepB+Hib), available at [http://www.unicef.org/supply/index\\_57476.html](http://www.unicef.org/supply/index_57476.html)

<sup>4</sup> Honduras co-finances \$0.30 each for two rotavirus doses, and \$0.15 each for three PCV doses.

<sup>5</sup> Comment at breakout session at 2010 Global Immunisation Meeting in Montreux, Switzerland, 23-25 June.

that had already been developed for wealthy markets. While pneumococcal disease does strongly affect poor countries, PCV has been sold in wealthy markets for over a decade.

The AMC incentivised companies to increase production of PCV to meet developing country demand, and offer the vaccine at a lower price per dose than available in wealthy markets. In exchange, companies' vaccines would be purchased by GAVI in pre-determined annual amounts over a ten-year period, provided country demand and GAVI funds were sufficient. The incentive to companies participating in the AMC comes in the form of a subsidy paid by donors, in addition to the price per dose paid by GAVI and purchasing countries.

Given high profits in wealthy markets - in 2008 Pfizer earned \$2.8 billion in annual revenue from the sale of an earlier version of PCV - the companies could have sold the vaccine to GAVI without receiving the subsidy. This is especially true given that increased production would lower the cost of vaccine manufacture through economies of scale.

Yet despite the highly lucrative market for PCV in wealthy countries, the two companies participating in the AMC, GlaxoSmithKline (GSK) and Pfizer/Wyeth, will each pocket an extra \$225 million in subsidy. These two companies will also be the only eligible candidates for the next round of AMC contracts, meaning they will receive even more of the total \$1.5 billion AMC pot.

The price of PCV is too high, and is a contributing factor to GAVI's financial troubles. PCV purchase alone represents 27% of the GAVI \$3.7 billion total funding shortfall.

Negotiated at \$3.50 per dose, the price of PCV could be lower and the quantities purchased greater, if competition existed. Emerging market manufacturers are developing PCV products and intend to sell them at considerably less. One company has set a target price which would be US\$2 per dose<sup>6</sup>. Instead of speeding up production of a low-cost vaccine and promoting competition, donor money has been locked into a decade-long arrangement that pays too high a price for a vaccine that already earns established pharmaceutical companies hundreds of millions of dollars in annual revenue.

## II – CONCLUSIONS AND RECOMMENDATIONS: WHAT DONORS NEED TO REQUIRE OF GAVI

Médecins Sans Frontières strongly supports GAVI's mission but urges donors to demand changes that will allow funds to be used more effectively.

GAVI claims that if donors commit to providing the requested resources for immunisation, by 2015 over four million children will be saved thanks to GAVI-sponsored vaccines. Funds would allow an additional 243 million children to be immunised, using vaccines against pneumococcal disease, rotavirus, Haemophilus influenzae type b (Hib), hepatitis B (HepB), and yellow fever, as well as ensure the complete roll-out of pentavalent vaccine.

Funding is therefore urgently needed. But it is important to recognise that this is what can be accomplished at existing prices—if prices were lower, more vaccines could be purchased and more lives saved. A telling example is the AMC subsidy payments and the cost of PCV. GAVI will purchase 286 million doses of PCV by 2015 to vaccinate 95.3 million children. Had PCV been available or negotiated at a price of \$2, the same amount of funds could have purchased over 500 million doses. And had \$1.5 billion in AMC funds gone toward direct purchase of PCV, rather than a subsidy scheme, an additional 250 million children could have benefitted from the vaccine at the \$2 price.

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<sup>6</sup> This US\$2 price was communicated to MSF by a leading emerging country developer/producer.

Alternatively, lower prices in the future could free up funds currently required for pentavalent, PCV and rotavirus for other important vaccines such as HPV and yellow fever. Price reductions take time to achieve, so it is crucial to start addressing high vaccine prices now.

To ensure increased funding commitments to GAVI will be used in a more effective manner, and more children in more countries will benefit from vaccines, MSF urges donors to condition funding increases to GAVI on implementation of the following:

### **1 – INCREASE PRICE TRANSPARENCY**

Part of the reason some countries end up paying substantially more than necessary for vaccines is the lack of public information available on prices. Without a good frame of reference for negotiation, countries pay too much. Recent price transparency efforts include publication of a UNICEF price database, which lists the vaccine suppliers and the prices they have charged UNICEF for their products for the past decade.<sup>7</sup>

Yet retrospective and future participation in UNICEF's database is optional for companies, and several large vaccine suppliers have chosen not to participate, including current and future GAVI Board Members, GSK and Crucell.

→ **DONORS MUST REQUIRE GAVI TO make vaccine prices paid by GAVI public.** Public price transparency has become a best practice for global health actors, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, that finance purchases of drugs and diagnostics.

### **2 – DEVELOP LONG-TERM STRATEGIES FOR MORE AFFORDABLE VACCINES**

Although the organisation has identified vaccine price reduction as one of its strategic goals, GAVI has so far failed to develop credible strategies to achieve this goal. External evaluation reports in 2005 and 2010 cited the inability of GAVI to lower vaccine prices as a “failing of the Alliance”.<sup>8</sup>

In order to achieve long-term price reductions, GAVI must promote competition, as well as the development of vaccines by emerging country manufacturers. These companies can not only sell vaccines at lower prices, but often are better-placed to create products that meet the needs of low-income countries. The development of the new Meningitis A conjugate vaccine relied on technology transfer to a southern producer, and created a product that is both affordable and appropriate for countries in Africa. GAVI needs to find methods of supporting emerging country producers to speed up development of adapted products rather than subsidise products created for wealthy markets.

→ **DONORS SHOULD INSIST THAT GAVI shape vaccine markets.** This is a strategic goal of GAVI, but so far, the effort has remained lacklustre. Credible strategies are required to increase transparency and speed up the entrance of competitive suppliers and better adapted vaccine versions. Evidence shows that competition is the best way to attain lower prices while still ensuring a secure vaccine supply. On the other hand, higher prices mean fewer children vaccinated and less impact of donor funds.

### **3 - REMOVE CONFLICTS OF INTEREST FROM THE BOARD**

Realisation of price transparency and shaping vaccine markets are highly dependent on eliminating conflicts of interest within GAVI. Arguably, the fact that pharmaceutical companies sit on the GAVI Board has handicapped GAVI in its efforts to lower prices or develop meaningful price strategies.

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<sup>7</sup> Available at: [http://www.unicef.org/supply/index\\_57476.html](http://www.unicef.org/supply/index_57476.html)

<sup>8</sup> “Second GAVI Evaluation Report,” 13 September 2010. Prepared by CEPA LLP, in association with Applied Strategies.

Interestingly, GAVI's own evaluations point to this fact, as the Evaluation Reports in 2005 and 2010 credit the lack of prioritisation of the issue to GAVI proclivity for "working strategically and proactively with industry Partners".

What is disturbing about the current GAVI dynamic is that the very companies that benefit from GAVI purchases also sit on the GAVI Board, and weigh in on GAVI policies that impact their revenue and profit. GSK is ending its term on the Board as the industrialised country vaccine producer delegate. While in this role, GSK has benefitted from the signing of the AMC, locking in at least \$225 million in subsidy, and hundreds of millions of dollars in revenues over the next decade. GSK will be replaced in May 2011 by Crucell, a subsidiary of Johnson & Johnson. Crucell is the largest UNICEF supplier of pentavalent vaccine, a vast majority of which will be bought with GAVI funds. One third of Crucell's annual revenue in 2009—\$143 million—came from sales to UNICEF.<sup>9 10</sup>

**→ DONORS MUST REQUIRE GAVI TO Remove conflicts of interest within GAVI by taking pharmaceutical companies off the Board of Directors and GAVI governance structures.** While we recognize and strongly encourage a permanent and structured dialogue between GAVI and the pharmaceutical industry, it must occur outside of GAVI governance bodies.

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<sup>9</sup> [http://crucell.com/annual\\_report\\_2009/overview/performance\\_highlights.html](http://crucell.com/annual_report_2009/overview/performance_highlights.html)

<sup>10</sup> [http://www.crucell.com/annual\\_report\\_2009/pdfs/management\\_report/Crucell\\_AR09\\_Report\\_of\\_the\\_Management\\_Board.pdf](http://www.crucell.com/annual_report_2009/pdfs/management_report/Crucell_AR09_Report_of_the_Management_Board.pdf)