Swine flu: Another lucrative pandemic

The government has started sending swine flu vaccines to GP's around the country, despite concerns over their safety and necessity for everyone. Frontline healthcare workers and high-risk patients had already started getting the Pandemrix jab, which is manufactured by Britain's largest pharmaceutical company, GlaxoSmithKline.

According to the the World Health Organization, as of last week nearly 5,000 people worldwide have died from swine flu since the disease emerged in April and developed into a global epidemic known scientifically as H1N1. In the UK, there have been about 128 deaths, mostly in England.

Meanwhile, global pharmaceutical giants have been competing to win contracts from national governments to sell their different versions of the swine flu vaccine. In Britain, two vaccines will be used: one manufactured by GlaxoSmithKline and the other by Baxter. It is understood that GSK's Pandemrix will be given to most people, while Baxter's Celvapan is being reserved for those with egg allergies as the GSK jab was made using a traditional method that involves chicken eggs.

Profits

GlaxoSmithKline has contracts to supply 290million doses of Pandemrix worldwide and expects more orders for its H1N1 vaccine. Britain had ordered a total of 132million vaccine doses (two per person) from both Glaxo and Baxter, but the exact amount ordered from each company is not known.

GSK is charging developed countries up to £6 for its vaccine and is set to make more than £1 billion in profit. Reports in July revealed each dose costs only £1 to produce. Glaxo, of course, denied it was exploiting the pandemic and claimed it had spent more than £1billion on vaccine technology in the past few years. Chief executive Andrew Witty said the company had been "preparing for a pandemic" for the last three-and-a-half years and had spent £1.2bn to ensure
its factories could "crank up production at short notice."

In 2005, former CEO J. P. Garnier is reported to have met US president George W. Bush to discuss pandemic flu planning. Since then, GSK has apparently taken steps to bolster its position in pandemic flu preparedness by investing in flu vaccine production facilities, the acquisition of vaccines production facilities and the development of candidate pandemic flu vaccines. "In a world where the only constant is change," the company writes on its website, "it takes forward thinking... to succeed."

Interestingly, Swiss drugs giant Novartis has recently brought a law suit against GlaxoSmithKline, claiming its biggest rival was infringing one of its patents concerning techniques used to produce a set of vaccines aimed at preventing childhood illnesses, including bacterial meningitis.

GSK will earn further millions by selling its swine flu treatment Relenza, production of which is to be tripled to 190 million doses a year by the end of 2009. It has also received approval for a new disposable antiviral face mask, which has apparently worked against previous strains of bird and swine flu. The mask has yet to be tested against the current swine flu strain.

Health and safety

As vaccination against swine flu has begun in many countries across the world, including the UK, the US and Australia, many questions regarding the vaccines' safety remain unanswered and many are worried that the race to test and produce the jabs may compromise their safety.

Back in 1976, around 48 million Americans were given a swine flu vaccine after the death of a US army recruit triggered fears of a repeat of the fatal 1918 pandemic. More than 530 of those vaccinated subsequently developed the Guillain-Barré syndrome, a neurological condition caused by rogue antibodies attacking nerve cells. Most people recover from Guillain-Barré, but not all. After 1976, 25 people, 10 cases per million vaccinated, died and others suffered lasting damage.

Health authorities insist that risks associated with swine flu vaccines have significantly diminished since then. Cases of Guillain-Barré in the US have fallen 20 percent since 1996 and cases reported after flu vaccination have fallen by 60 percent. [1]

Another potential worry are the immune-stimulating chemicals called adjuvants, which are added to some vaccines, including Glaxo's Pandemrix, to stretch their active ingredient and increase the human body's immune response. According to the New Scientist, the World Health Organization asked countries to make pandemic vaccines with adjuvants because much less of the key ingredient, dead flu virus, would be needed per dose, meaning far more doses can be produced (see here [1]). The US could not apparently do this because no seasonal flu vaccines with adjuvants have been tested and approved there. In Europe, however, there have been, so the main pandemic vaccines being given in Europe, Pandemrix and Focetria, do contain adjuvants. The adjuvant in Glaxo's swine flu vaccine, known as adjuvant system AS03, has been used in more than 41,000 people in bird flu, swine flu and regular flu vaccines.

All swine flu vaccines have had their own safety tests -although some would say not enough- and almost all are based on seasonal flu vaccines. Experts argue that very rare side effects may not be detected unless the vaccine is tested on a very large number of people. The
seasonal flu vaccines with adjuvants have mostly been given to older people, so we cannot yet be sure that these vaccines do not have rare side effects in younger people.

According to the BBC, Sir Liam Donaldson, the government’s chief medical officer (who last week said the timing of the postal strike was ‘unhelpful’ as GPs receiving swine flu vaccines would be sending out appointment letters in the post) admitted the vaccine had been produced “more quickly than usual” but denied it had been rushed and stressed it was “safe.”

GlaxoSmithKline only started testing its vaccine in August. In July, the company said that clinical trials “will be limited” due to “the need to provide the vaccine to governments as quickly as possible.” “Additional studies,” it added, “will therefore be required and conducted after the vaccine is made available.” In other words, it will be tried on a mass scale on real people, and without their permission.

GSK has launched a Clinical Trial Register, offering clinical trial data that anyone can access. The website can be found at http://ctr.gsk.co.uk. [2]

**One dose or two?**

Last week, mainstream media reports made a lot of fuss over concerns by ‘drug regulators’ that one dose of the swine flu vaccine may not be enough. The Telegraph, for example, wrote: “Drugs regulators have recommended that two doses of the swine flu vaccine are used despite British health officials deciding to go ahead and give one dose on most cases.”

All that the European Medicines Agency’s Committee for Medicinal Products for Human Use had said, in fact, was that “evidence was not strong enough to recommend one dose for general use.” In other words, one dose may be sufficient but the evidence so far is not conclusive enough. In additional notes on Pandemrix, the Committee said, “The vaccine should preferably be used as a two-dose schedule, but a single dose may be sufficient in adults aged 18 to 60 years. Consideration can be given to using the same one-dose schedule in adolescents and children (over the age of ten years).”

In a statement on Friday, and based on data from a trial in Spain in 200 children aged six months to three years, Glaxo said one dose was enough to boost children’s immune systems to fight the virus. The UK government, however, had already ordered enough vaccines for the whole population to have two doses, which raises questions about how and why this decision was taken. A detailed look at Glaxo’s Board of Directors may provide some hints.

**GSK**

GlaxoSmithKline plc (GSK) is the UK’s largest pharmaceutical company, formed in 2000 through the merger of Glaxo Wellcome and SmithKline Beecham. Headquartered in Brentford, West London, the company operates in some 114 countries, mainly in two areas: pharmaceuticals (prescription pharmaceuticals and vaccines) and consumer healthcare. GSK’s principal pharmaceutical products include medicines in the therapeutic areas, such as respiratory, central nervous system, anti-virals, anti-bacterials, metabolic, vaccines, cardiovascular and urogenital, oncology and emesis. In 2008, GSK reported a total turnover of £24bn, with operating profits exceeding £7bn.

Glaxo markets over 25 vaccines worldwide for such illness as hepatitis A and B, diphtheria, tetanus, whooping cough, measles, mumps, rubella, polio, typhoid, influenza and bacterial meningitis. The majority of its vaccine research and development activities are conducted at
GlaxoSmithKline Biologicals in Rixensart, Belgium, with some 1,300 scientists devoted to developing new vaccines. The company claims that, every hour, it spends more than £300,000 to find new medicines and brags it has "a track record of turning research into powerful, marketable drugs." GSK has recently 'reorganised' its research and development efforts into so-called Centres of Excellence for Drug Development (CEDDs), which are small business units emphasising "flexibility, innovation and therapeutic focus."

Glaxo's Board of Directors includes five Sir's out of a total of 13 members. Among these is Sir Christopher Gent, a non-executive chairman, who is a former CEO of Vodafone Group Plc. and served as the National Chairman of the Young Conservatives from 1977 to 1979. He is also a non-executive director of Lehman Brothers Holdings Inc and of Ferrari SpA.

Another is Sir Roy Anderson, also a non-executive director, who until September 2007 was the Chief Scientific Adviser at the Ministry of Defence. He received a knighthood in the Queen's birthday honours in June 2006 and, in 2008, became the rector of Imperial College.

On the Board also is James Murdoch, who joined GlaxoSmithKline in 2008 as a non-executive director and member of the company's Corporate Responsibility Committee. The son of media mogul Rupert Murdoch is chairman and chief executive of News Corporation Europe and Asia and non-executive chairman of BskyB.

The real story, however, is in Glaxo's chief executive's bio. Andrew Witty, who assumed the position of Chief Executive Officer in May 2008, has served in numerous advisory roles to governments around the world, including South Africa, Singapore, Guangzhou China and the UK. He is currently a non-executive director of the UK's Office for Strategic Co-ordination of Health Research; sits on the Imperial College Commercialisation Advisory Board; is a member of the Health Innovation Council and of INSEAD UK Council. He is also a member of the Business Council for Britain; a board member of PhRMA; a vice-president of EFPIA and a member of the Singapore Economic Development Board's International Advisory Council. It wouldn't surprising, then, that the government's decision to rush Glaxo's vaccine may have somehow been influenced by this wealth of government-industry relations.

[1] It might be worth noting that there are a number of conspiracy theories about swine flue vaccines circulating around. For example, see www.theflucase.com [3] and www.drcarley.com.
[4]