

2010 and vaccine industry growth. Its more than H1N1.....

LONDON, UK----11th March 2011----ExpertREACT. Once again pandemic influenza vaccines sales boosted the industry* in 2010 which grew by another 15-20%. Companies are keen to state the strength of their underlying businesses driven mainly by expansion into non-US/EU markets and widening seasonal influenza vaccine recommendations. Significant near-term upside remains in meningitis.

According to our recent calculations, the top 5 vaccine players* sold around \$22bn worth of vaccines in 2010 compared to nearly \$19bn in 2009. On both comparable and non-comparable terms this is an impressive year-on-year sales increase of approximately 18%. In fact, looking back at sales in 2003 (~\$6bn), the top 5 players have now nearly quadrupled their business in 7 years experiencing a CAGR (2003-2010) of again ~19%. It is almost becoming a cliché to mention the vaccine industry, compared to other healthcare sectors, is growing strongly. The underlying factors are well known to even the most “lay” of observers. Nevertheless, it is still valuable to tease out some of the key drivers, which contributed to 2010 being another successful year.

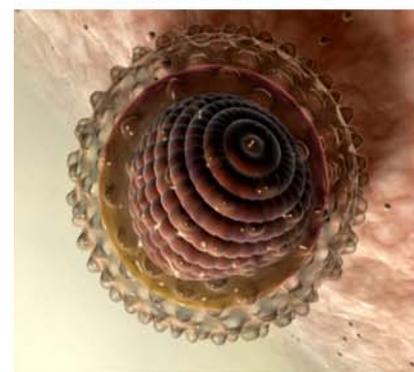
One of the most surprising observations of 2010 was the continued strong contribution of pandemic influenza vaccine sales. We estimate that, for the top 5 vaccine players, the segment contributed around \$3.7bn of revenues, an increase of ~\$700m over the figure recorded in 2009. Most of 2010 sales were realized in Q1 as “carry over” from the previous year, however, GSK, the largest beneficiary from the pandemic, still recorded around \$360m worth of sales in Q3/Q4 of 2010; a figure almost similar to its seasonal influenza franchise (Fluarix/FluLaval) in the same period (1).

Remaining on the theme of influenza, 2010 was a good year for the seasonal business. Dominant seasonal flu player: Sanofi Pasteur reported record results for seasonal vaccines at €845m (FY 2010), a 33% increase on 2009 at constant exchange rates (2). The widening of US recommendations, and the likely “awakening” of the general public to the importance of vaccination; post H1N1, contributed to a remarkable 54.4% increase of sales in the key US market, where the company states it now has greater than 50% market share. Overall Sanofi sold 320 million doses of influenza vaccines (pandemic + seasonal) in 2010. In all segments Sanofi also reported strong growth in emerging markets – its now biggest region.

In dollar terms, GSK Biologicals sold the most in 2010 with \$6.7bn revenues. While sales in the EU and US markets remain static, or experienced marginal declines, GSK is also on track to enlarge its footprint in “Rest of World” and emerging markets. Both now have reached ~\$1.4bn (FY 2010), exceeding sales in the US. GSK is keen to point out that its underlying vaccine business (excl pandemic) is also growing at a double digit rate (1). For newsflow so far in 2011, GSK stated that its 10-valent *pneumococcal* vaccine, Synflorix would be the first rolled out in Africa (Kenya) as part of the advanced market commitment (AMC) program (3); a landmark achievement considering the historical lag of entry for other life-saving vaccines in developing nations. GSK also announced March 2nd, that it had submitted a Marketing Authorisation Application (MAA) to the European Medicines Agency (EMA) for its quadrivalent *meningococcal* vaccine (ACWY), Nimenrix (4). Globally, Nimenrix will compete head-on against similar products being offered now by both Novartis (Menveo) and the incumbent, Sanofi Pasteur (Menactra).

On reported terms Novartis Vaccines & Diagnostics experienced strong growth (~20%, \$2,9bn) over 2009 sales, still benefiting from the legacy of H1N1. The division sold \$1.3bn of H1N1 vaccines/adjuvants in 2010, and like GSK, is also keen to state its underlying business continued to grow strongly (+16%), at constant exchange rates. It is becoming increasingly difficult to ascertain the components of the Novartis vaccines business itself because the parent Novartis AG does not reveal much in its released material. However, we believe the vaccines division itself would have most likely crossed the \$2 bn mark in 2010. Novartis did state but in July 2010 that it intended to supply 40 million doses of Fluvirin to the US 2010/11 influenza season (5), a large increase on the previous season due to monovalent vaccine production. Flud, Novartis’ adjuvanted influenza vaccine was also filed for the pediatric population in 2010.

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Beyond flu, Novartis' fortunes rest heavily with its emerging meningitis vaccine franchise. For Menveo, quadrivalent *meningococcal* vaccine (ACWY), the company reports a resource intensive global roll-out but still not product specific sales. Menveo, received FDA-approval for children from 2 years of age in late January (6) but, like its competitor GSK's CY/Hib, is meeting resistance penetrating the all important infant use segment (2 mos to 2 yrs). Novartis received a FDA Refuse To File (RTF) letter for Menveo in this group. Novartis' other foray into meningitis prevention with the new serogroup B vaccine "Bexsero" was filed for regulatory review in Europe late 2010 (7). In many countries the argument for infant serogroup B prevention (in terms of case numbers) is more convincing than ACWY. The progression of Novartis' all encompassing ABCWY vaccine into mid Phase II testing is an interesting observation.

Paradoxically Pfizer and Merck & Co tend to receive less attention in our articles due to their low or non-involvement in the eventful influenza business and relatively "thin" R&D pipelines. For 2010, Pfizer reported a huge \$3.6bn revenues for its Prevnar/Prevenar 7/13 franchise and Merck & Co reported ~\$1bn in Gardasil sales, albeit reduced on 2009. Both Pfizer and Merck & Co also have strong intentions in emerging markets – cliché number 2.

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***Top 5 companies:** GSK Biologicals, Sanofi Pasteur, Merck & Co, Pfizer (Wyeth) and Novartis Vaccines and Diagnostics

References and Notes:

- 1) GSK Corporate website. Fourth quarter 2010. February 3rd 2010.. Available at: http://www.gsk.com/investors/quarterly_results.htm Accessed March 2011.
- 2) Sanofi-aventis. Corporate Results FY 2010. February 9th 2010. Available at: http://en.sanofi-aventis.com/events/2010_Results/docs/20110209_Results2010_slides.pdf. Accessed March 2011
- 3) GSK Corporate Press Release. 2nd March 2011 Regulatory update: Nimenrix. Available at: http://www.gsk.com/media/pressreleases/2011/2011_pressrelease_10036.htm Accessed March 2011.
- 4) GSK Corporate Press Release. 11th February 2011 Available at: First African country introduces GSK's pneumococcal vaccine through innovative financing mechanism. Available at: http://www.gsk.com/media/pressreleases/2011/2011_pressrelease_100226.htm Accessed March 2011.
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