

2011 FY results – vaccine industry waiting for the next burst of growth

LONDON, UK----24th February 2012----ExpertREACT. Sales of vaccines in 2011 were mostly unchanged on 2010 due to the disappearance of H1N1 and price cuts due to increasing competition and austerity programs. Only brand new vaccines e.g. dengue and *meningococcal* serogroup b will give the industry its next burst of significant growth.

According to our calculations, the top 5 vaccine players* reported around \$20.8bn worth of vaccines in 2011 compared to nearly \$22bn in 2010. The figures, which are in non-comparable terms i.e. using different exchange rates for each year suggest the industry remained flat or even slightly decreased in 2011. Because GSK reports in GBP Sterling and Sanofi Pasteur in Euro calculations between different analysts are subject to variation depending on methodology chosen.

Although now some time ago the 2009 H1N1 “swine flu” pandemic continues to affect company figures with the key suppliers GSK Biologicals, Sanofi Pasteur and Novartis Vaccines, who benefited the most in 2009/2010, seeing decreases in 2011 reported sales over 2010 (in dollar terms). This **ExpertREACT** article will briefly cover each company individually to see how they fared in 2011 and key anticipated events for 2012.

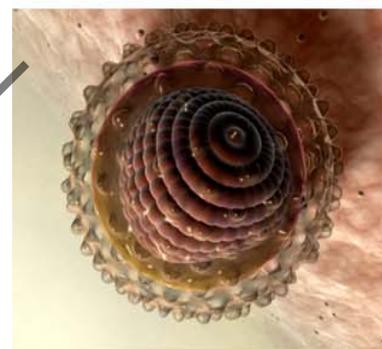
In dollar terms, GSK Biologicals sold the most in 2011 with \$5.63bn revenues (1) but sales in all regions: Europe, Emerging Markets and Rest of World except the USA all declined when calculated in constant exchanges (CER%). GSK sold £18m of pandemic vaccines in 2011 compared with over £1bn in 2010 and its seasonal franchise (Fluarix, FluLaval) was mainly flat/declining due to pricing pressure. One of main growth products was the bivalent HPV vaccine Cervarix® which recorded £506m compared to £242m in 2010. Cervarix® continues to benefit from the national HPV vaccination program in Japan which includes a catch-up phase of five cohorts. In other franchises declines were often attributed to price cuts due to government austerity programs which undoubtedly having an impact across the whole industry.

In product development news, GSK recently received positive opinion in Europe from the Committee for Medicinal Products for Human Use (CHMP) on Nimenrix®, a conjugate vaccine for invasive *meningococcal* disease caused by *Neisseria meningitidis* serogroups A, C, W -135 and Y (2). Nimenrix®, which is approved for individuals >12 mos of age will join Sanofi's Menactra and Novartis Vaccines' Menveo which collectively sold around \$730m in 2012. Both incumbents recognize the majority of their sales driven US ACIP recommendations for adolescents. In other markets sales are mainly related to “at risk” vaccination and/or pilgrims to the Haj. GSK will grab a share of this potential market but without a significant product advantage will need to spend to gain a decent foothold.

Sanofi Pasteur recorded €3,469m of vaccine sales in 2012 (3). The company states there was an underlying increase of 7.2% excluding H1N1 sales and a 5.5% decrease if the latter were included. Sanofi stated it experienced a record year for seasonal influenza vaccines with total sales of €826m in part driven by stronger sales in the Southern Hemisphere. In emerging markets and Rest of World regions where the company is keen to dominate, sales now account for around ~40% of total. Apart from Travel and Other endemics vaccines all other Sanofi vaccine franchises grew over 2010 at constant exchange rates.

For product development, Sanofi's Phase III dengue vaccine (CYD) is a significant program for the company and indeed, for the industry overall. 1st preliminary efficacy results from a Phase IIb study in Thailand (n=4000) are expected by the end of 2012 with an ambitious filing plan as early as 2013. According to our analysis the potential market for a dengue vaccine is sizeable (4) with potential blockbuster revenues attainable in the mid-term. The closest competitor to Sanofi is Inviragen's DENVax which has recently initiated Phase II studies in Latin America in relevant age groups (5). Inviragen claim a possible advantage linked to a 2 rather 3 dose schedule which could be advantageous in terms of schedule inclusion although this needs to be borne out by further clinical studies.

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Merck & Co had a good 2011 with a reported 22% increase in its lead product the quadrivalent vaccine Gardasil (7). Gardasil sold \$1.2bn in 2012 helped by a new indication for males. Rotateq, Pneumovax and Zostavax all showed strong increases on 2010, although ProQuad, MMR11 and Varivax collectively showed a decline. Back in November 2011, Merck, which is normally a little muted regarding vaccine R&D, gave a presentation regarding its pipeline (8) and listed in Phase III, a new nine-valent HPV vaccine (V503), an inactivated Herpes Zoster vaccine (V212) and a pediatric hexavalent combination vaccine (V419). Earlier in development the company is also investigating a Pneumoconjugate vaccine (V114).

Pfizer's formidable PCV-7/PCV-13 franchise registered \$4145m in 2011 (an increase on 2010) of which \$3657m was due to PCV-13. The company's lifecycle management plan to drive uptake in >50 years is seemingly meeting some resistance at the US ACIP committee which recently met (Feb 22,23rd) as the company put out a press release strongly advocating the recommendation (9) and sticking with its current financial guidance. Lastly Novartis Vaccines and Diagnostics reported around \$2bn in revenues for 2011 (10). The company still awaits an EU decision on Bexsero® its meningococcal serogroup B vaccine.

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

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