

2013 FY results – QIVs a highlight in a flat industry

LONDON, UK----6th February 2014----ExpertREACT. Strong growth in influenza vaccines even after a partial switch to QIVs does little to lift a flat vaccine industry in 2013

According to our calculations, the top 5 vaccine players* reported around \$20.7bn worth of vaccines in 2013 compared to nearly \$21.4bn in 2012. The figures, which are in non-comparable terms i.e using different exchange rates for each year suggest the industry experienced a modest decline (~3%) in 2013. Average exchange rates for the Euro and British pound against the US dollar were not significantly different during 2013 and 2012, suggesting the decline is real.

This is the third year running that we have held the view that the vaccine industry is essentially flat and waiting for its next burst of growth. It appears that life cycle management initiatives i.e. conversion to Quadrivalent format in flu vaccines are driving pockets of growth which do not fully offset declines in other segments such as HPV vaccines [GSK], meningitis, pneumococcal and adult booster vaccines. Only the launch of brand-new products matched to new national immunisation programs (NIP) will add billions to overall industry value.

This **ExpertREACT** article will discuss the fortunes of the five major vaccine players during 2013 and examine any potential highlights for the coming year.

Again in dollar terms, GSK Biologicals again sold the most out of the major players in 2013 with \$5.37 bn revenues (1). The company stated that performance of the vaccine business was up 2%, with a significant increase in tender sales of Synflorix (Brazil) and Infanrix/Pediarix (Europe/EMAP) in Q4. Cervarix declined 37% because of the vaccine suspension in Japan. One notable highlight was the commercial benefit of new Quadrivalent (QIV) influenza vaccines (Fluarix/Flulaval) which are priced 30 to 40% higher than their trivalent equivalents. For Q4, in the US, Fluarix/FluLaval sales more than doubled to £36 million and globally up 76% at £87m. GSK's Nimenrix, a relatively new product sold £12m in 2012. Pipeline highlights for 2014 could be GSK's Phase 3 programs for malaria, MMR and Zoster.

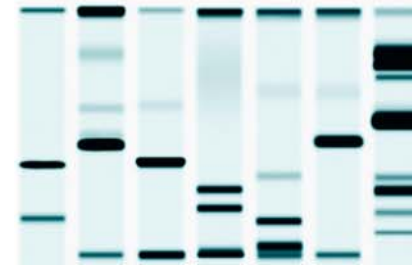
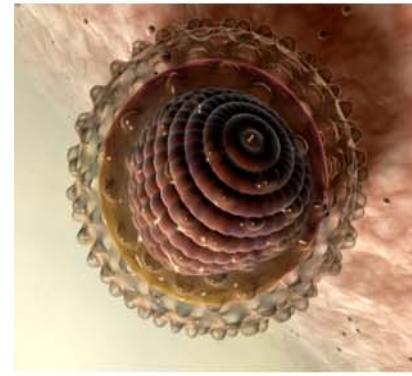
Sanofi Pasteur recorded €3,716m of vaccine sales in 2013 compared to €3,897m of vaccine sales in 2012 (2) a decrease of 4.8% in reported terms. The company cited strong influenza vaccine sales, which recorded an impressive 94.4% increase in the fourth quarter of 2013. In the important US market, sales were threefold higher than the last quarter of 2012, reflecting the success of Sanofi's life cycle enhancements to its influenza portfolio. New flu vaccines such as the high dose, intradermal and Quadrivalent formulations now represent 41% of its US influenza vaccine sales versus 26% in the previous year. Considering that Sanofi's supplied volume of Quadrivalent vaccine was lower than competitors such as GSK & Medimmune, these figures are likely to be further improved for 2014. Despite the good news in flu, other segments such as meningitis and booster vaccines experienced double-digit declines on the year, although travel and other vaccines experienced strong growth. For 2014, we await further R&D progress on two novel vaccines for dengue and *Clostridium difficile*.

Novartis Vaccines and Diagnostics reported \$1987m sales for 2013 an increase on the \$1858m recorded in 2012 (3). Again Novartis cited strong growth for Menveo its conjugate vaccine for invasive *meningococcal* disease (ACWY) but also pre-pandemic (H7N9) and seasonal influenza sales despite not yet switching to a Quadrivalent format which is actively in development. A small amount of private sales for *meningococcal* serogroup b vaccine were also recorded partly due to University outbreaks in the US e.g. Princeton. The company still waits any further evaluation from the UK JCVI regarding the possible implementation of the UK immunisation programme despite the same committee previously stating the vaccine *wouldn't be cost-effective at any price*.

Because the vaccines and diagnostics division remains loss-making unit for its corporate parent a number of times, senior Novartis personnel have mentioned, they are in discussions to divest the unit, which was acquired back in 2007. The company is known to be in discussions with Merck & Co as part of a possible trade for its OTC drugs business (4). Other bidders, most likely the other vaccine major players will be considering the unit behind-the-scenes.

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Unlike its European rivals Merck & Co experienced growth in all of its vaccine franchises in 2013 (5). Gardasil, Zostavax and Pneumovax recorded double-digit growth of 12%, 16% and 13% respectively. Although the Japanese suspension of HPV vaccination also affected Gardasil, the product saw good growth in emerging markets. Despite initial supply problems, the UK decision to implement the shingles vaccine programme for >70 yrs is positively impacting upon Zostavax sales. Merck & Co still focuses on late stage vaccine R&D programs V212 (Herpes Zoster), V503 (HPV related cancers) and V419 a new pediatric hexavalent combination.

Lastly Pfizer's PCV-7/PCV-13 franchise registered \$3974m in 2013 a decrease on the \$4267m recorded in 2012 & \$4145m recorded in 2011 (6). The company's aged-based lifecycle management plan for its *pneumococcal* franchise doesn't yet seem to be driving a significant uptake in sales although Merck's Pneumovax continues to grow. Topline results from Community-Acquired Pneumonia Immunization Trial in Adults (CAPItA) 65 years of age and older may improve matters. In terms of R&D Pfizer also mentioned in its analyst call that they anticipate sharing results from Phase 2 studies of Staph aureus and meningitis B vaccines at medical congresses later in 2014.

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

References and Notes:

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