

2015 FY Results – Pfizer grows the vaccine industry

LONDON, UK----16th March 2016----ExpertREACT. Pfizer proves that effective life-cycle management can bring substantial commercial rewards *via* its PCV/PCV-13 franchise. Can Sanofi and GSK do the same but with new products?

According to our analysis, the vaccine industry major players* sold just over **\$23.3 bn** worth of vaccines in 2015. In non-comparable terms, this is an increase (~4%) over the ~\$22.2 bn we reported this time last year for FY 2014. Currency exchange movements have offset figures, to some extent, but also the way sales are reported affects things slightly. The old Novartis Vaccines business is now reported by GSK Biologicals (excl influenza) and the newly named entity Seqirus (formerly BioCSL) which reports influenza; it's figures in a half yearly format. Next year, sales from the EU joint venture, SPMSD (not included) will revert to the respective parent companies.

British based **GSK** reported £3,657m worth of vaccines sales compared to £3,192m at the end of 2014, a 19% increase (1). The company mainly benefited from the sales of newly acquired meningitis products from the Novartis acquisition namely, Bexsero (menB) and Menveo (menACWY), which grew 43% (£275m over \$195m in 2014). Both of these vaccines were driven by new recommendation decisions by the UK government but also the private market for Bexsero. Other products such as Boostrix and the MMRV portfolio saw gains due to competitor shortages but in turn, the re-entry of a competitor affected the Infanrix/Pediarix franchise in the US. GSK stated that the performance of their Fluarix/FluLaval franchise had improved over 2014. This was due to a 30% increase in US supply capacity over 2014-15 and a full switch to the higher priced quadrivalent format (QIV). The influenza franchise sold £268m in FY 2015.

In their FY 2015 presentation, GSK reiterated the success of their differentiated shingles vaccine candidate, Shingrix (AS01 adjuvanted) which has shown 90-97% efficacy in two Phase III studies in >50 yrs. **GSK** is currently preparing to submit regulatory filings for Shingrix in North America, Japan and the EU, expected for the second half of this year. Considering that Merck & Co's Zostavax sold around \$750m in 2015, with lower efficacy and poor coverage (<25%) it is of little surprise that **GSK** see big potential rewards with their new vaccine. The company forecasts ~25-30m doses of Shingrix by 2020 (2).

Sanofi Pasteur reported €4,743m worth of vaccines sales in 2015, an increase of 7.3% over the previous year (at constant exchange rates) (3). The company stated it had a record year for influenza vaccines with over 66m doses sold in the US. Now 90% of all US flu vaccines are of a differentiated format e.g. Fluzone® HD and Fluzone® Quadrivalent and Fluzone® Intra-Dermal which brings improved price per unit sold. 2015 net sales of flu vaccines were €1,322m up 25% in the fourth quarter.

Apart from its travel/endemic and influenza franchises, **Sanofi** reported mostly double digit growth rates across its varied portfolio. Notable increases were of Polio/Pertussis/Hib vaccines, which increased 13.5% to €466 million driven by sales of Pentaxim® in China and sales of Menactra®, which increased 16.3% to €104 million in the fourth quarter driven by booster vaccinations in the U.S. In 2015, Menactra® delivered a strong performance with sales up 18.2% to €563 million. Sanofi expects a significant revenue enhancement from its first in class vaccine to prevent dengue fever, **Dengvaxia**. The vaccine was approved in late 2015 in three countries, Mexico, the Philippines and Brazil but no sales were recorded in Q4 2015. The vaccine is expected to reach blockbuster status as regulatory decisions are now expected in a further 16 countries.

Merck & Co reported approximately \$6 bn worth of vaccines sales in 2015, an increase on the previous year (4). The company's Gardasil/Gardasil-9 franchise (\$1.9 bn) saw an increase of 10% on 2014 with most of the sales (~90%) being of the original Gardasil product. In 2016, the company should see a US-based increase in Gardasil-9 due to the FDA decision to approve an expanded age indication to include use in males 16 through 26 years of age for the prevention of anal cancers, precancerous or dysplastic lesions and genital warts. **Merck & Co** experienced declines in the sales of Pneumovax-23 to \$542m due to increased competition from Pfizer's PCV-13 in the adult/elderly segment. Unfavourable exchange rate movements affected to some degree the sales of Zostavax and Rotateq although MMR-II vaccines were lifted due to higher demand (measles outbreaks) and pricing in the US.

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Pfizer vaccines recorded a massive increase in worldwide revenues of its Prevnar/Prevenar 13 franchise (5). The products recorded \$6,245m in 2015, an increase of 40% over 2014 (\$4,464m). In the U.S., revenues for Prevnar increased 87% in 2015, compared to 2014, mainly due to continued strong uptake among adults following the positive recommendation from the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) for use in adults aged 65 and older. Revenue increases were much smaller at 9% in the international region which was also affected by the strengthened dollar. Pfizer vaccines also reported \$104m in sales for the ex-Baxter vaccine product FSME-IMMUN/TicoVac and an additional \$298m in other "V/O" sales, which includes vaccines (TRUMEMBA, other) and oncology.

Pfizer states that the adult PCV-13 "catch-up" opportunity has yet to be fully realised in the US, also adult use of the vaccine in the EU and International region is likely minimal although the vaccine does reduce CAP and IPD in >65 yrs. Therefore, the Prevnar/Prevenar 13 franchise could grow further. Although the company has an active R&D pipeline –more so in recent years–the company has proved that effective lifecycle management of a single vaccine can bring substantial rewards, especially in the growing elderly segment. GSK hopes to achieve the same with Shingrix but also in the evolving maternal segment (RSV/GBS). Sanofi is targeting the global endemic market via Dengvaxia. But our bets are with Pfizer, there are plenty of older (and richer) people in the West to protect against the continual threat of pneumococcal disease.

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**GSK Biologicals, Pfizer, Sanofi Pasteur, Merck & Co and Seqirus, excludes SPMSD sales*

References and Notes:

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