2016 FY results – the impact of 'real use' and true product innovation

LONDON, UK----10th April 2017----ExpertREACT. The yearly vaccine industry still operates in the same $ range, lifted by intermittent boosts of life-cycle management. 'Real use' data has favoured the truly innovative, Bexsero. Will it do the same for Dengvaxia?

According to our analysis the top 4 vaccine manufacturers* *(excl SPMSD)* sold around **~$23bn** of vaccines for the full year in 2016, a figure barely changed from FY 2015. In fact, if one looks back, the industry has operated in the $20-23bn/yr revenue range since 2010#. Historically, big gains have occurred: the launch of Gardasil US (2006), the H1N1 pandemic (2009/10) and PCV-13 life-cycle management (2014/15), but many of these are not sustained. How will the industry move into higher territory and experience its growth witnessed 2003-2009? This **ExpertREACT** will cover the FY 2016 results per competitor and point to any growth spots.

In US dollar terms, **GSK Biologicals** sold the most in FY 2016, reporting $6,245m revenues (£4,592m) **(1).** GSK states that sales grew 14% on a reported basis. Across all regions, increases were also in the double-digit range. The serogroup b *meningococcal* vaccine, **Bexsero** (acquired from Novartis, EU approved 2013) stuck out with strong yearly sales of **$530m** (est >10m doses global in 2 years). Strong growth of private channel sales in the EU/LATAM became a good supplement to the public UK infant program. Note: the vaccine sold $175m in FY 2015.

In the US, the ACIP permissive recommendation for menB in adolescents also drove uptake with ~30% of global sales recorded ($166m)–even more so than the menACWY counterpart, **Menveo** which recorded ($165m). 'Real world' effectiveness data of 83% case reduction in the first year of the UK infant program **(2)** has bolstered Bexsero's profile significantly. In other areas, GSK cited higher demand for Encepur (TBE), Rabipur (rabies) and its flu products Fluarix/FluLaval but mentioned that growth was offset by unfavourable stocking and competitor actions for certain other products.

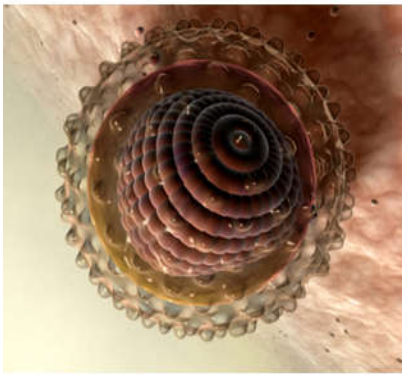
Looking forward, GSK stated (November 2016) that it has filed its new Shingles vaccine, **Shingrix** in the US, Europe, and Canada. It expects a filing in Japan, H1 2017. Shingrix is a non-live recombinant vaccine to help prevent shingles and its complications. The vaccine will compete head-on with Merck & Co's Zostavax live vaccine which sold ~$750m in 2015. GSK is optimistic with Shingrix openly stating the product should drive ~1/3 of their growth to 2020 **(3).**

Sanofi Pasteur reported €4,577m of vaccine sales in FY 2016 up 3.7%, mainly driven by the PPH/AcXim franchises (+16.5%) **(4)**. In the EU sales fell 46.3% but mainly due to deferring SPMSD sales as part of a buy-back program. For influenza, although US sales declined 14% in the fourth quarter, overall the company stated the franchise delivered a record year with €1,521m sales and 70m doses shipped in the US.

Sanofi's 'first in class' dengue vaccine, **Dengvaxia** only sold €55m in FY 2016. Despite being approved in 14 countries, only two regional based programs have been initiated (Parana, Brazil and Regions III, IVA and NCR, Philippines). The remaining sales have been made through private channels. Dengvaxia's first year has been disappointing, but for the moment it is the only vaccine until ~2020 when rivals from Takeda Vaccines and NIAID/Merck & Co/Instituto Butantan may be licensed. 'Real use' experience from Brazil and/or Philippines may elevate country adoption of the product. Undoubtedly, the WHO SAGE restrictive recommendation of >9 yrs (high seroprevalence settings) along with funding constraints in badly affected countries has caused hesitancy among national policymakers.

In R&D and registration stages, Sanofi has 16 projects many of which are lifecycle management initiatives although ***Clostridium difficile*** (Phase III), another 'first-in class' vaccine has an expected complete in December of this year (NCT01887912). Notably, Sanofi also has a Zika vaccine candidate (WRAIR), RSV and HSV-2 programs all in Phase I development signalling its commitment to new vaccine innovation.

We calculate that **Merck & Co** sold $6.2bn worth of vaccines in FY 2016, an increase of 10% over 2015 **(5)**.



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Pneumovax-23 ($641m) and Gardasil-9 ($2,173m) global roll-out drove sales higher based on new vaccination guidelines, higher pricing, and demand. A switch to a two-dose format for Gardasil, however, is expected to impact upon sales in the US.

Zostavax has a near term threat from GSK's new **Shingrix** although the company also has an inactivated VZV candidate, V212 at Phase II clinical stages. Other investigation vaccines are for Ebola (V920) and a newer pneumococcal conjugate (V114).

Pfizer vaccines reported $6,071m revenues in FY 2016, a decline on the $6,454m on the year earlier **(6)**. Most of the decline was attributable to the Prevnar/Prevenar-13 franchise in the US coming to the end of the exploitable phase of the adult (>65yrs) 'catch-up' opportunity. The company states that ~50% of the eligible patient pool has already been vaccinated and the remainder of the opportunity is more difficult to access. Slight decreases in the franchise were also observed in Emerging Markets, Developed Europe and Total International regions.

For Pfizer's ex-Baxter and smaller products, FSME/IMMUN-TicoVac and the 'other' category posted increases on FY 2015 of $10m and $135m, to record $114m and $239m respectively. It is likely based on GSK's Bexsero's performance that Pfizer's menB vaccine, **Trumenba** is also gaining revenue momentum, although not made explicit by Pfizer. In R&D, Pfizer has announced it will progress its *Clostridium difficile* vaccine [PF-06425090] into Phase 3 in the first half of 2017.

A critical observer might argue that in the past years, the vaccine industry (top 4 players) has posted moderate gains off the back of life-cycle management initiatives rather than truly innovative products. Good examples of LCM are in the bigger product segments such as influenza (QIV), human papilloma virus (HPV-9) and *pneumococcal* vaccines (>65 yrs). Before seeing the FY 2016 performance of GSK's **Bexsero**, admittedly this viewpoint held some weight. Bexsero, approved in 2012 (EU) has taken some time, but now it can no longer be considered a minor product (>$500m/yr). Bexsero is only part of one major funded national immunization program (United Kingdom) and must be attracting private customers. This sounds rather like the early days of **Dengvaxia.** If Sanofi can show that vaccine significantly reduces the impact of dengue in Brazil and Philippines, 'real use' data should also lift that product. There will always be a future for true vaccine innovation.

**GSK Biologicals, Sanofi Pasteur, Merck & Co and Pfizer vaccines*
 # GSK Biologicals and Sanofi Pasteur report in £GBP and € respectively which have fluctuated against the dollar

Sources: Corporate Press Releases and the below

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