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### The global influenza vaccine market – where next?

**LONDON, UK----18<sup>th</sup> May 2016----ExpertREACT.** Value growth of the US flu vaccine market is now entrenched and predicted to continue, but what about elsewhere? The UK childhood program could set a new precedent in Europe.

The yearly influenza vaccine market is a significant business. Roughly speaking it accounts for around a quarter of all sales to the vaccine industry and for some major suppliers, such as Sanofi Pasteur, the segment accounts for a quarter of revenues. Our latest global influenza model (1) indicates that each year (in 28 countries) around ~500m doses are distributed, a figure usually cited elsewhere by the World Health Organization (2) and other academic publications (3). If one summates the reported revenues of key suppliers: around \$2bn of sales occur in the US market and globally, most likely \$4bn and upwards.

Valuation of the global market is a challenging task. Not all manufacturers report specific influenza revenues but we hope the Seqirus acquisition of the ex-Novartis flu business will add some further transparency to the long suffering market analyst. In 2014, GSK stated that the ex-Novartis influenza business was worth \$527m during its negotiations for other parts of the ex-NVS portfolio. Recently Seqirus said it supplied 56m doses to the US market in 2015/16, therefore its true revenues by region or even product may become visible soon. Outside the West, transparency falls even further but we discover that fairly accurate volume predictions can be achieved.

Underlying dynamics suggest that global demand for influenza vaccines should be increasing. Our population is aging, so the volume of doses consumed by the elderly (>60 or 65 yrs) segment therefore predictably shows an upward trend. This is also relevant because most countries exhibit their highest vaccine coverage rate in this group and the vaccine is usually free of charge (or reimbursed). An OECD publication last updated in 2011 indicated that the average coverage rate in the elderly across 27 countries was 56.5% (4). Surprisingly vaccination rates in 2009 were below this average in major economies such as Japan, Denmark, Portugal and Ireland. One would assume that rates have improved further since this time. Notably, in the USA 2014-15 the rate was 66.70% >65 yrs (5) which still has room for improvement since in 2009 Mexico and Chile had much higher rates >88%.

Harmonization with the US > 6 mos universal recommendations should also theoretically increase global demand for influenza vaccines. In our analysis we have identified that quite a number of countries, even in the "Rest of World" category operate some form of childhood influenza vaccination policy. However, the most striking example of a move to childhood influenza vaccination has to be that announced by the United Kingdom in 2013. The UK Joint Committee on Vaccination and Immunization (JCVI) decided to extend flu vaccination to children aged 2 to under 17 yrs in a phased program over a number of years (6).

The underlying rationale of the UK program was that extending the current flu vaccination program to all children aims to lower the public health impact of influenza by 1) protecting children and thus averting a large number of cases of flu in children and 2) reducing flu transmission in children thus protecting older adults and those with clinical risk factors and averting many cases of severe disease and flu-related deaths.

Analysis of 2014/15 UK data suggests that the program has had some moderate success with 30-40% coverage in the 2, 3 and 4 yrs old groups amounting to a further ~830,000 persons vaccinated in primary care (7). Beyond this, children aged 5-7 yrs were added in the 2015/16 season with improved coverage rates (~55%), possibly due to their school attendance. If one considers the lifetime of the program and these current data, the program could vaccinate ~6m children per year by 2021/2022 (with various assumptions). Furthermore, using this data and bearing in mind the UK recommendation that AZ/MedImmune's Fluenz-Tetra (LAIV) is the vaccine of choice in this group and GSK's Fluarix-Tetra for those contraindicated to LAIV (UK Green Book) (8) one can estimate the eventual fortunes of these suppliers to the UK program.

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Considering that AZ/MedImmune has seen an increase in its Western European sales from \$42m in 2014 to now \$76m in 2016 the effect of the UK program is now being visualized. Conversely in the US, the company saw a decrease in sales over FY2014 due to supply issues. US fortunes are not expected to increase for AZ/MedImmune as it recently announced at the 2016 National Adult and Influenza Summit that it would only produce 14m doses of Flumist for the US 2016/17 season (9). Also the US ACIP dropped its preferential for LAIV in children (10).

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Many cite the value growth of the US influenza market in recent years. The reasons are quite straightforward being the switch to higher price QIV and high-dose products such as Fluzone-HD which have improved average prices per unit sold. We predict this upward trend is expected to continue as the last major supplier Seqirus stated it would switch to QIV in the 2017/18 season (currently under review) and Fluzone-HD is expected to convert to a QIV form. But what about outside the US where differentiated products have been far less adopted? One potential goldmine would be if the other major European economies instigated a UK like program for its 2-17 yrs group. Although maybe not imminent, if such a dynamic came to pass for AZ/Medimmune (if it could keep up with supply) it would more than double its current revenues. Maybe if the UK program (which still prefers LAIV) shows huge benefits from its implementation other governments would follow? We will wait and see.

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

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