Meningitis vaccines dominate US and UK headlines

LONDON, UK----02nd July 2015----ExpertREACT. Recent news confirms that the meningitis vaccine segment will transform to a multi product, multi region business in both ACWY and B serogroup forms. For Pfizer and GSK – let the battle commence!

June 2015 has been a busy month for news headlines focused on vaccines to prevent *meningococcal* disease. Public sector decision-making bodies on either side of the Atlantic have progressed the implementation of national immunisation programs for *meningococcal* serogroup B and ACWY vaccines and, in the corporate sector, Pfizer vaccines have acquired GSK's legacy *meningococcal* vaccines from its earlier acquisition of Novartis' vaccine business.

In the UK, protracted negotiations regarding the provision of meningococcal serogroup B vaccine finally prompted an official announcement that from 1 September 2015 all babies in England and Scotland at two months, four months and 12 months would receive the vaccine, Bexsero (1). There will also be a limited catch-up programme for babies who are due their 3 and 4-month vaccinations in September so they are also protected when they are most at risk of Men B infection. The main delay from the original Joint Committee on and Vaccination Immunisation (JCVI) decision in March 2014 has been the issue of price and cost effectiveness, which were finalised on 29 March 2015. The national immunisation programme should dramatically affect the 1200 or so cases each year in the UK, and more importantly, set a worldwide precedent for this new childhood vaccine. Studies of the vaccine have predicted that it will cover approximately 88% of MenB circulating in the UK (2), and 78% of MenB in Europe over all (3).

The UK authorities also announced that from August 2015, all 17- and 18-year-olds in school year 13 and first-time university students up to the age of 25 will be offered the Men ACWY vaccine. There will also be a catch-up vaccination programme for current school year 10 students through schools from January 2016. And the Men ACWY vaccine will also be added to the routine adolescent schools programme (school year 9 or 10) from Autumn 2015, alongside the 3-in-1 teenage booster, and as a direct replacement for the Men C vaccination (4). This comprehensive vaccination strategy mirrors to some extent a programme in the US, which has been ongoing since 2005. The main thrust behind the UK decision is the observation that cases of meningitis and septicaemia due to Men serogroup W have been increasing in England, from 22 cases in 2009 to 117 in 2014. The increase seems to be accelerating in 2015, caused by an aggressive strain (cc11, IMD). Again, the UK programme will be precedent-setting for the European continent where apart from risk groups, and travelers in to the Hajj - age-based use of menACWY is very limited e.g. Austria and Greece recommend a single dose of vaccine for adolescents. Nimenrix (Pfizer) and Menveo (GSK) menACWY vaccines are available in the EU.

In the US, the Advisory Committee on Immunization Practices (ACIP) gave a "category B" recommendation for meningococcal serogroup B vaccination in young adults (preferred age groups 16 through 18 yrs of age). This means that the decision will be left to doctors and their patients rather than a blanket recommendation for everyone in a particular age group or risk factor group (5). Previously, in MMWR weekly, use of the serogroup B vaccines in persons greater than 10 yrs at increased risk from B meningococcal disease were also published as guidelines (6). Example risk groups include those individuals with persistent (i.e. genetic) deficiencies in the complement pathway (prevalence 0.03% in the population). This causes up to 10,000 fold increase risk of meningococcal disease, with the possibility of recurrence.

In terms of the full ACIP recommendation "category A", some committee members were concerned about the safety aspects of the new serogroup B vaccines, Bexsero (GSK) and Trumemba (Pfizer). Serogroup B vaccines are more reactogenic than other vaccines given during adolescence, although the majority of local and systemic reactions were mild-to-moderate in severity and transient (7). Currently in the US, there are no recommendations for meningococcal vaccines, in healthy infants.

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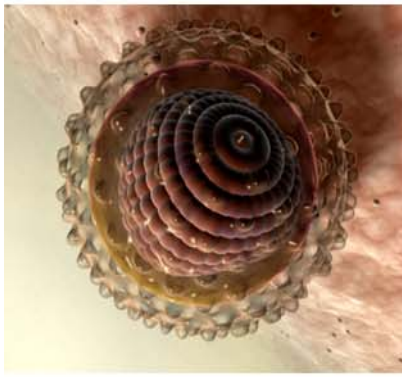

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The emergence of new, significant policy recommendations in *meningococcal* vaccines coupled with M&A activity in the corporate sector makes for some interesting discussions regarding that the future competitive environment in this market segment. Taking 2013 as an example year, for menACWY vaccines, the market (~$782m) was chiefly composed of US sales, which in turn were dominated by Sanofi Pasteur's Menactra (8). The fact that Menactra is not approved in the EU, and the possibility that other EU countries may harmonize with the UK stance, it is a logical prediction that GSK and Pfizer will now fight head-on to capitalise on a growing EU market, and possibly – if Argentina and Brazil at the vaccine to an NIP. For meningococcal serogroup b vaccines, due to lack of data, Pfizer has no potential in future infant NIPs but will again fight rival GSK's Bexsero in the US adolescent market at a disadvantage (3 dose versus 2 dose schedule). The most interesting observation on our part is that both companies have the necessary building blocks to develop a pentavalent an ACWYB vaccine for adolescents. GSK must have known this when they divested Nimenrix-ACWY to Pfizer – but being already in Phase II with this approach (9), it seems they are also confident Pfizer aren't much of a threat.

References and Notes:

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