

2015 – The year of meningitis vaccines

LONDON, UK----2nd December 2015----ExpertREACT. In 2015, meningitis vaccines dominated industry headlines. They were part of new product development, company acquisitions, used in outbreak measures and part of brand new infant national immunization program in the United Kingdom.

At first glance, even to the outsider, 2015 was a busy year for the vaccine industry. Now, as the year ends, it is a good time to look back at the main events and discuss how they could shape the industry moving forward. This **ExpertREACT** article will discuss the vaccine industry in 2015 with a particular emphasis on the major players: Pfizer, GlaxoSmithKline, Merck & Co and Sanofi Pasteur. Novartis Vaccines no longer exists; the loss making division was acquired by GSK earlier in March in a three-part transaction with corporate parent Novartis Pharma.

In terms of number of press releases related to vaccines GSK Biologicals and Pfizer Vaccines far exceeded their rivals Merck & Co and Sanofi Pasteur which partner in Europe under the SPMSD brand. In fact, upon analysis of the news releases we could say that 2015 was “the year of meningitis vaccines”. Not only were meningitis vaccines involved in new product development, they were also part of acquisitions, new governmental recommendations and a brand new infant national immunization program in the United Kingdom. Coupled with these developments, a meningitis vaccine, MenAfrivac continued to have a massive impact upon the disease in sub-Saharan Africa. Meningitis vaccines truly save lives and this year reminds us the pathogen remains as unpredictable and dangerous as ever.

Over recent years, *Neisseria meningitidis* outbreaks have fortuitously made investment in preventative vaccines for companies more attractive – even those that previously exited the space. Pfizer Vaccines, for example once had a meningitis C vaccine, *Meningitec*, that it divested to Nuron back in 2012 (1). The company re-entered the segment in 2015 with both monovalent C (NeissVax, Baxter Vaccines) and two quadrivalent ACWY products, Nimenrix (conjugated) and Menecavax (polysaccharide) (GSK Biologicals, divestment) (2). These acquired products fully compliment its now marketed product Trumenba for *meningococcal* serogroup B that gained US FDA approval in October 2014 (3) and a permissive ACIP recommendation for adolescents and young adults 16 through 23 years of age (4). Rival GSK possesses Bexsero (4CmenB) and Menveo (conj-ACWY) from its Novartis Vaccines acquisition.

US outbreaks of *meningococcal* B disease in US universities at Princeton and UC, Santa Barbara brought the importance of serogroup B vaccination to the forefront of policy maker’s minds with hundreds vaccinated before actual vaccine approval. In Canada, a virulent serogroup B clone (ST269) which emerged in Quebec in the Saguenay-Lac-Saint Jean region (SLSJ) in 2003 with a disease rate more than 10 times the Canadian average (3.6/100,000 person years) added to the impetus. All outbreaks hastened approval of both Pfizer’s Trumenba and GSK’s Bexsero (4CmenB). However, in our mind, 2015 brought the most significant development: the UK government’s decision to implement a new infant immunization program (using 4CmenB) starting in September 2015 (5). The Men B vaccine is now recommended for babies aged 2 months, followed by a second dose at 4 months, and a booster at 12 months. The program will be the first of its kind in the world. Approximately 800,000 infants are born each in the UK; hence Bexsero will graduate from a niche emergency like product to a significant revenue stream. In the 9 months to September 2015 Bexsero sold £78m of which £58m were derived in EU. In 2016, Bexsero revenues should be in the hundreds of millions.

In 2015, the UK government also made brand new recommendations for quadrivalent conjugated ACWY vaccination in adolescents. Before, such widespread recommendations in the northern hemisphere were limited to the US, which brought a pioneering program to adolescents back in 2005 (6). In the UK, the reason for the increase was a steady increase in invasive meningococcal disease due to serogroup W of the ST-11 clonal complex associated with high case fatality. The same clone has caused similar issues in South America and South Africa. For the UK program, which began in August 2015, 17 – 18 year olds (school year 13) and older university entrants (aged 19 – 25) will be offered one dose of the vaccine in primary care (GP).

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The same age groups will also be offered the vaccine in 2016 and 2017. From spring 2016 the Men ACWY will replace Men C, which is currently offered to year 9 or 10 (depending on local arrangements). This school-based programme will also provide a catch-up to include pupils in year 11 (15 and 16 year olds) (7).

Although vaccination for meningitis serogroup with MenAfrivac (meningococcal A conjugate vaccine) started back in 2011, 2015 saw the addition of six more countries to the program: Ethiopia, Democratic Republic of Congo, South Sudan, Uganda, Eritrea and Kenya. Approximately 315 million people have been targeted for vaccination across the meningitis belt, with the entire population—an estimated 450 million (8). MenAfrivac has proved to possess a good safety profile and has induced a dramatic reduction of carriage and invasive disease in vaccinated districts among both vaccinees and non-vaccinees. Ultimately, countries would ideally need the vaccine to protect birth cohorts as currently only mass campaigns are planned.

2015 also brought new developments for meningitis in Africa. Reports from Niger's Ministry of Public Health to the WHO of ~6000 suspected cases of meningococcal meningitis, including 406 deaths from January 1st to May 2015 were mainly caused by serogroup C (9). This is the first large-scale meningitis outbreak caused by serogroup C to hit any country in Africa's meningitis belt. It seems *Neisseria meningitidis* will never fail to surprise us. We hope it doesn't in 2016.

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References and Notes:

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