Who will benefit from the predicted boom in inactivated polio virus vaccines?

LONDON, UK----1st October 2013----ExpertREACT. In a new report* **VacZine Analytics** models the size of the potential market for inactivated polio virus vaccines (IPV) and discusses opportunities for current producers.

**OpportunitySCAN: inactivated poliovirus vaccines (CAT No: VAOPS004, Autumn 2013)*

Poliovirus, a member of the *Picornaviridae* family has the potential to cause irreversible paralysis in children < 5yrs, with 5 to 10% mortality. Fortunately, the number of polio cases has decreased 99% since 1988 **(1)**, as a result of vaccination. Now only 3 countries (Afghanistan, Nigeria and Pakistan) remain polio-endemic in 2013, although polio free countries remain at risk of importation of wild poliovirus from these countries (Note: outbreaks in Somalia, Ethiopia and Kenya).

Much of the success in eradicating polio has been due to the launch of the Global Polio Eradication Initiative (GPEI) **(2)**, launched in 1988 and coordinated by national governments and supranational partners such as the WHO, Rotary International, the US Centers for Disease Control and Prevention (CDC), UNICEF and the Bill and Melinda Gates Foundation. It is estimated that the GPEI has invested more than $8 billion so far to achieve its goals with net health benefits predicted to be US$40 billion to US$50 billion over the two decades following eradication **(3)**. Recently the GPEI has published the Polio Eradication and Endgame Strategic Plan 2013–2018, which through four objectives seeks to deliver a polio free world by 2018. These objectives are 1) Detect and interrupt all poliovirus transmission 2) Strengthen immunization systems and withdraw oral polio vaccine 3) Contain poliovirus and certify interruption of transmission and 4) Plan polio's legacy.

Achieving Objective 2) is multifaceted and extremely complex. Firstly, the GPEI proposes a switch from trivalent (Sabin) oral poliovirus vaccine (tOPV) to a bivalent form (bOPV). This is because, although the oral poliovirus vaccine has many advantages of low-cost, ease of administration and mucosal immunity, it can generate Vaccine-derived polioviruses (VDPVs), which can cause paralysis and circulate in a similar manner to wild poliovirus. Most VDPV cases are caused by the type 2 component of OPV hence the logic to switch to bOPV, which only contains types, 1 and 3 forms of virus and is more efficacious than tOPV. OPV also carries the risk of vaccine-associated paralytic poliomyelitis (VAPP) which occurs in an estimated 1 in 2.7 million children receiving their first dose of oral polio vaccine.

Beyond the switch from tOPV to bOPV, which should occur by 2015, the GPEI also states that the 97 countries, which use OPV schedules (3 doses, < 6 mos) should then introduce at least one dose of inactivated polio vaccine (IPV) into their NIPs in 2015. Presently only high income countries use IPV (Salk based, normally as part of combination vaccines), which is not as immunogenic as OPV, but does not cause VAPP. IPV also is not as convenient to administer, being given by intramuscular injection and is far more expensive. A 2009 report suggested that IPV manufacturing costs in the future will still be 4 to 15 times that of OPV **(4)**. IPV does not stop poliovirus transmission risking continued circulation, but its global introduction will re-address global susceptibility to Type 2 poliovirus instigated by the earlier switch of tOPV to bOPV.

Meeting the GPEI objectives outlined above will prove to be an expensive exercise. Therefore there is a large emphasis on attaining a low-cost IPV, which realistically cannot fall substantially below $1 per dose, and will "never" reach a price equal to that of OPV **(4)**. Stakeholders have suggested various options to decrease the price of IPV such as volume purchasing/guaranteed procurement, antigen sparing approaches i.e. intradermal fractional IPV dosing, alternate cell lines (PER.C6) and the use of Sabin IPV. However, at present there is a lot of uncertainty as to whether these options will actually reduce the price of IPV. There are also the added complications of countries wishing to produce the IPV locally, the number of IPV doses needed and whether IPV would be a stand-alone addition to an immunisation programme or part of a combination product. In any case, by the end of 2013 it should be clearer whether GAVI can subsidise the introduction of IPV, GPEI have earmarked $322m (2013-18). In addition, the latest viewpoint from the WHO SAGE committee should be available.

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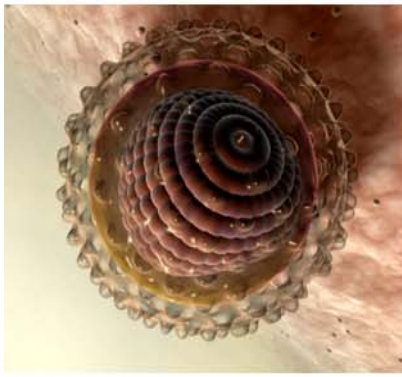

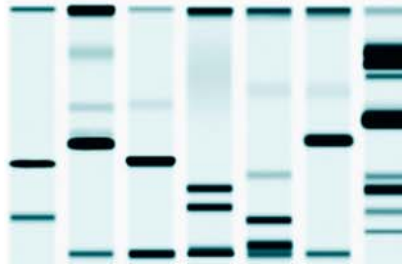

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Who will benefit from the boom in inactivated polio virus vaccines? Sanofi Pasteur and GlaxoSmithKline are the leading manufacturers of Salk-IPV. Indeed, Sanofi Pasteur is a WHO "global preferred partner" for IPV gaining WHO prequalification in 2005. Other producers of Salk IPV are the Serum Institute of India Ltd , who acquired Bilthoven Biologicals in July 2012 **(5)** and the Statens Serum Institute (SSI). Interestingly, the Serum Institute of India fired the first shot in a potential price war with Western producers of Salk-IPV by agreeing to supply IPV at ~$1.70 per dose, with possible further reductions **(6)**.

The WHO has encouraged the production of Sabin-IPV based on non-infectious attenuated Sabin seed-strains that are safer (in terms of containment failure) for IPV production in developing countries. This could allow countries to produce locally rather than source Salk IPV from the four main suppliers. In 2012, two Sabin-IPVs were approved in Japan (Japan Poliomyelitis Research Institute) demonstrating Sabin-IPV is as safe and effective as Salk-IPV. It is not clear whether Sabin-IPV could be produced more cheaply than Salk-IPV, but among other things this dynamic indicates that the market is not necessarily "sewn up" by the large Western producers.

*__Top 5 companies:__ GSK Biologicals, Sanofi Pasteur, Merck & Co, Pfizer (Wyeth) and Novartis Vaccines and Diagnostics

References and Notes:

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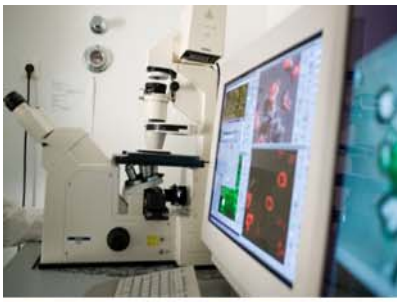

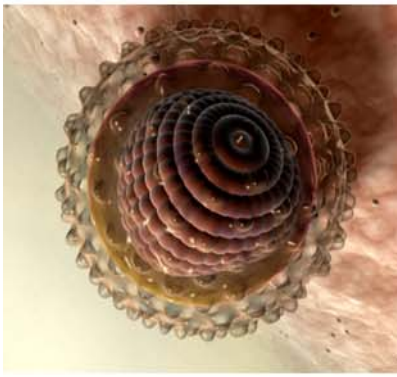

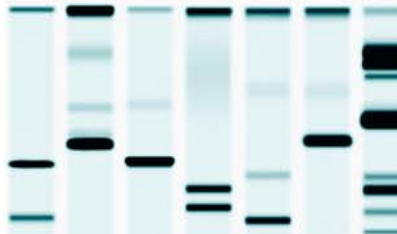

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