

GSK announce meningitis vaccine for Africa

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British pharmaceutical giant GlaxoSmithKline (GSK) have announced the development of a vaccine for use in African meningitis belt countries that the company says will never make a profit¹ or even recoup its R&D costs. The vaccine is Globorix[™], primarily a conjugate meningitis A & C vaccine, which will also protect children against other diseases such as diphtheria, tetanus and hepatitis B.

The demand for approval of Globorix[™] was made under article 58 of the EMEA (European Medicines Agency) regulation 726/2004 which allows a company to ask the agency for a scientific opinion on the efficacy, quality and safety of a medicinal product for use exclusively outside the EU in cooperation with the WHO. This procedure is designed to help developing country medicines agencies to approve much needed medicinal products.

According to Jean Stéphenne, President of GlaxoSmithKline Biologicals, the development of Globorix[™] reflects "GSK's long-standing commitment to the developing world" and meets "a pressing public health threat in Africa".

Anyone who has followed the "access to healthcare" debate in the years since the 2001 South African court case², will notice that GSK has done exactly what pharmaceutical companies have been criticised for not doing; namely developing products to tackle health problems faced by poor countries whose health systems and people will never provide a lucrative market. The main customers for Globorix[™] are likely to be the WHO and NGOs providing healthcare to poor people in African meningitis belt countries.

But what do other stakeholders say? Dr Tido von Schoen Angerer, Executive Director of Médecins Sans Frontières (MSF)'s Access to Medicines programme welcomed the announcement but noted that neither future availability nor pricing of Globorix[™] were yet clear. He explained that MSF was concerned that before the new GSK vaccine becomes available, there will be shortages of the traditional polysaccharide meningitis vaccine as GSK have stopped making it, leaving Sanofi-Pasteur as the world's sole manufacturer. Dr von Schoen Angerer also noted that GSK charge a relatively high price in developing countries for Rotarix[™], a paediatric vaccine against Rotavirus. "If GSK charge a similarly high price for Globorix[™], it will be a shame" he said.

Meanwhile, an unnamed blogger asks whether Globorix[™] will be "a loss leader"³, presumably believing GSK is more interested in creating a market for its products than meeting developing country healthcare challenges.

Is this the shape of things to come? Well at least one other similar project is already

¹ <http://www.gsk.com/ControllerServlet?appld=4&pagelid=402&newsid=1006>
<http://news.bbc.co.uk/2/hi/health/6508985.stm>

² When 39 pharmaceutical companies challenged provisions of section 15 C the South African Medicines and Related Substance Control Amendment Act of 1997 resulting in hostile publicity driven by NGOs like Oxfam, MSF and TAC and ending with an "amicable" (out of court) settlement, the text of which can be found at: <http://news.bbc.co.uk/2/hi/africa/1285645.stm>

³ <http://scienceoftheinvisible.blogspot.com/2007/03/globorix-gsk-good-pharma-or-bad-pharma.html>

underway, in the form of cooperation between the (private) Serum Institute of India and the health NGO PATH which saw successful completion of phase I clinical trials of a conjugate vaccine against serogroup A meningococcal meningitis⁴ last year. Serum/PATH have already announced a price of \$0.40 per dose for their vaccine.

These developments raise many questions. Is this the new way forward for meeting the health needs of the developing world? Is there really such a thing as a non-profit pharmaceutical product? If so, will we see more similar projects in the future? Or if not, is this more cynically, simply a pharmaceutical industry ploy designed to create markets for their products? The author of this article reserves judgement for the moment, but is sure that these questions will reignite the pharmaceutical CSR debate for some time.

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⁴ <http://www.path.org/PATHImprovedmeningitisvaccineforAfrica.php>