

# FISH HOEK VALLEY RATEPAYERS & RESIDENTS ASSOCIATION

*(Incorporating Fish Hoek, Clovelly and Sun Valley)*

**P.O. Box 22125, Fish Hoek 7974 – Tel: 084 3999933**

**Web : <https://www.fishhoekratepayers.com/> Facebook : [www.facebook.com/FHVRRA/](https://www.facebook.com/FHVRRA/)**

**TO: [NompumeleloM@daff.gov.za](mailto:NompumeleloM@daff.gov.za)**

**SUBJECT: OBJECTION TO GLAXOSMITHKLINE BIOLOGICALS SA'S  
APPLICATION TO USE GMO VACCINE AGAINST PAEDIATRIC  
RESPIRATORY SYNCYTIAL VIRUS**

---

## 1. DISCUSSION

GlaxoSmithKline Biologicals SA has applied for the intended use of GMO vaccine in South Africa to be used as a paediatric respiratory syncytial virus (RSV) vaccine (ChAd155-RSV) from a chimpanzee-derived adenovector. RSV is problematic mainly for the very young and very old. Exposure to RSV does not lead to long-lasting protection and hence people can have many infections over their lifetime.<sup>1</sup> RSV is extremely seasonal with peaks in the main two mid-winter months. Previous studies have shown a 100% vaccine schedule to infants less than six months to not be cost-effective.<sup>2</sup> The African Centre for Biosafety (ACB) warns that GMO vaccines are still experimental and may even make the subject more susceptible to RSV. Adenoviruses are problematic and unstable. One has to test for replication competent adenoviruses (RCA) shedding. Also, post-trial monitoring with tumourigenicity and toxicology studies must be carried out. Basically, the risks are unknown.<sup>3</sup> As the Genetically Modified Organisms Act #15 of 1997, amended in 2007, seeks the **reduction of the potential risks** arising out of activities involving the use of genetically modified organisms, we cannot condone this application to use a GMO vaccine.

As this trial pertains to humans and thus, invokes the National Health Act #61 of 2003 and the Medicines and Related Substances Amendment Control Act #90 of 1997, other players should also form part of this panel to safeguard the dignity, rights, safety and wellbeing of all trial participants.

## 2. RECOMMENDATIONS

It is recommended, for the reasons set out in this report, that:

- This application **BE DENIED**; and
- The following groups should be on a joint decision panel:
  - Health and Environmental Affairs Departments,
  - Medicines Control Council and

---

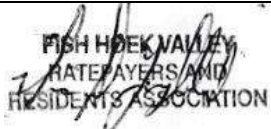
<sup>1</sup> Domachowske J, Rosenberg HF "Respiratory syncytial virus infection: immune response, immunopathogenesis, and treatment." in Clin Microbiol Rev. 1999; 12: 298-309

<sup>2</sup> [https://www.thelancet.com/journals/lanpub/article/PIIS2468-2667\(17\)30103-2/fulltext](https://www.thelancet.com/journals/lanpub/article/PIIS2468-2667(17)30103-2/fulltext)

<sup>3</sup> <https://acbio.org.za/wp-content/uploads/2015/02/gmvaccinesbooklet.pdf>

- Research Ethics Committee

For vetting before any further GMO applications for public participation are advertised.

<b>NAME &amp; SURNAME</b>	<i>Brian Youngblood, Chair: Fish Hoek Valley Ratepayers and Residents Association (FHVRRA)</i>
<b>CONTACT NUMBERS</b>	Cell: 084 3 99 99 33
<b>E-MAIL ADDRESS</b>	<a href="mailto:bdyoungblood@gmail.co.za">bdyoungblood@gmail.co.za</a>
<b>SIGNATURE</b>	
<b>DATE</b>	23 May 2019