Lelystad, 28th of January 2018.

Press Release

Short summary of the view of The European GMO-free Citizens of the 11th of December 2017 with later supplements in 2018 because of an application for a clinical trial with a GM vaccine. So, it is an introduction into the environment of GMOs. It is an application of the Antoni van Leeuwenhoek Ziekenhuis (Hospital) in Amsterdam. Mark IM-MV 17-004. The Dutch Ministry of I&W is the authority to give permission, but has not given her final permission yet. (1)

Newborns from South-Africa as guinea pigs.

So, we, The European GMO-free Citizens, (De Gentechvrije Burgers) have written a view with supplements against an application for a clinical trial with a GM vaccine (*Recombinant BCG VPM1002BC, Clinical study title: A Phase I/II Open Label Clinical Trial Assessing Safety and Efficacy of Intravesical Instillation of the Recombinant BCG VPM1002BC in Patients with Recurrent Non-Muscle Invasive Bladder Cancer after Standard BCG Therapy Clinical Study Code: SAKK 06/14*).

Formerly stages of this experimental vaccine (*VPM1002, still with hygromycin in it, an antibiotic resistant gene, as VPM1002BC does not contain it anymore)* were given as a TB vaccine to German subjects, South Africans of indigenous African descent and to **Newborns from South-Africa. (2a)**

Oral polio vaccine mandatory.

These newborns both boys and girls must be vaccinated with an oral polio vaccine and other vaccines, this contains aluminum (3). More and more scientific articles describe, that this might cause autism. (4).

Not ethical.

We are shocked and believe that this is not ethical. The genetic engineering vaccine on these children is still in the experimental stage. Although the mothers gave their consent, did they know it was a GM vaccine? *"The possible risks, any benefits for the patients and other medical ethical aspects associated with clinical studies are reviewed by The Dutch Central Committee on Research Involving Human Subjects (CCMO).* We read this text in every **Beschikking** *(=. Commission decision)* of the Ministry of I&W*.*

Unfortunately, in our view, this application is not properly assessed by this Commission and they should never have approved this application. We believe this trial is in violation of Directive 2001/20/EC, considerations 2, 3 and 6 (5).

Letter by Dr. Andriukaitis

Fragment of the letter that we received as an attachment by email by Dr. Andriukaitis, European Commissioner for Health and Food Safety after we did send him an email about this topic*:*

"…….during the assessment of an application for the authorization of a clinical trial the relevant national authorities in the Member State where the application has been submitted also assess whether any clinical trials conducted outside the EU, and which relate to medicinal products intended to be used in the EU, are designed, implemented and reported on the basis of good clinical practice and ethical principles that are equivalent to the provisions of Directive 2001/20/EC. Such clinical trials should also be carried out in accordance with the ethical principles that are reflected, for example, in the Declaration of Helsinki."

Other tests with vaccines against TB on newborns in SA failed, previously tests on monkeys raised doubt, some of the monkeys died, parents did not know.

We learned about earlier tests on newborns that appeared in South-Africa: ***(clinical trial gm vaccine, MVA85A* also against TB*)***.

On the10th of January 2018 The British Medical Journal wrote*:* *Oxford vaccine study highlights pick and mix approach to preclinical research. Researchers were disappointed when a clinical trial of a new tuberculosis vaccine failed to show benefit, but should it have gone ahead when animal studies had already raised doubts and what does it mean for future research? Deborah Cohen investigates.*

Fragment page 5: Were trial participants misled? *But perhaps of greatest concern is whether parents of babies enrolled in the MVA85A trials were misled. Parents of participants were told that: "MVA85A has been tested in animals and was shown to be safe and effective." Volmink is critical of the information provided.* Comment British Medical Journal, 10-01-2018. More see (6).

Footnotes.

(1) SNIF version 2, June 2017 (Summery Notification Information Format).
https://www.gentechvrij.nl/wp-content/uploads/2017/12/IM-17-004-Adam-snif.pdf
SNIF version 3, August 2017 (Summery Notification Information Format).
https://www.gentechvrij.nl/wp-content/uploads/2018/01/IM-17-004-snif-aug-17.pdf

(2) *Study to Evaluate the Safety and Immunogenicity of VPM1002 in Comparison With BCG in HIV-exposed/-Unexposed Newborn Infants in South Africa* https://clinicaltrials.gov/ct2/show/NCT02391415
Max Planck Gesellschaft: *"On the way to a new tuberculosis vaccine. VPM1002 is being tested in clinical trials as a tuberculosis vaccine in newborns and as a drug against cancer of the bladder".* March 23, 2015. https://www.mpg.de/9066544/tuberculosis-vaccine
Power Point Presentation: http://www.tbvi.eu/wp-content/uploads/2016/02/Presentation-Leander-Grode_web.pdf Feb. 13, 2016.

(2a) Clin Vaccine Immunol. 2017 Feb; 24(2): e00439-16.
Safety and Immunogenicity of the Recombinant Mycobacterium bovis BCG Vaccine VPM1002 in HIV-Unexposed Newborn Infants in South Africa
André G. Loxton,a Julia K. Knaul,b Leander Grode,b Andrea Gutschmidt,a Christiane Meller,b Bernd Eisele,b Hilary Johnstone,c Gian van der Spuy,a Jeroen Maertzdorf,d Stefan H. E. Kaufmann,d Anneke C. Hesseling,e Gerhard Walzl,a and Mark F. Cotton[illegible]f, the VPM Study Group.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5299117/
https://clinicaltrials.gov/ct2/show/NCT00749034 Phase 1a Trial (Germany)
https://clinicaltrials.gov/ct2/show/NCT01113281 Phase 1b Trial (South Africa)
https://clinicaltrials.gov/ct2/show/NCT01479972 Phase II Open Label, Randomized, Controlled Study to Evaluate Safety and Immunogenicity of VPM1002 in Comparison With BCG in HIV-unexposed, BCG Naive Newborn Infants in South Africa.

(3) Adjuvants and Inactivated Polio Vaccine: A Systematic Review
Jennifer Hawken, BSa,* and Stephanie B. Troy, MD.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3529007/pdf/nihms414738.pdf

(4) The Daily Mail and the Hippocratic Post write on the 30th of November 2017:
'Perhaps we now have the link between vaccination and autism': Professor reveals aluminium in jabs may cause sufferers to have up 10 times more of the metal in their brains than is safe.
By Professor Chris Exley For The Hippocratic Post and Alexandra Thompson Health Reporter For Mailonline.
Read more: http://www.dailymail.co.uk/health/article-5133049/Aluminium-vaccines-cause-autism.html#ixzz525SvvcjX https://www.hippocraticpost.com/infection-disease/aluminium-and-autism/

(5) **Directive 2001/20/EC**

Featured considerations, 2.3, and 6:

Whereas:

2. The accepted basis for the conduct of clinical trials in humans is founded in the protection of human rights and the dignity of the human being with regard to the application of biology and medicine, as for instance reflected in the 1996 version of the Helsinki Declaration. The clinical trial subject's protection

is safeguarded through risk assessment based on the results of toxicological experiments prior to any clinical trial, screening by ethics committees and Member States' competent authorities, and rules on the protection of personal data.

3. Persons who are incapable of giving legal consent to clinical trials should be given special protection. It is incumbent on the Member States to lay down rules to this effect. Such persons may not be included in clinical trials if the same results can be obtained using persons capable of giving consent. Normally these persons should only when there are grounds for expecting that the administering of the medicinal product would be of direct benefit to the patient, thereby outweighing the risks. However, there is a need for clinical trials involving children to improve the treatment available to them. Children represent a vulnerable population with developmental, physiological and psychological differences from adults, which make age- and development- related research important for their benefit. Medicinal products, including vaccines, for children need to be tested scientifically before widespread use. This can only be achieved by ensuring that medicinal products which are likely to be of significant clinical value for children are fully studied. The clinical trials required for this purpose should be carried out under conditions affording the best possible protection for the subjects. Criteria for the protection of children in clinical trials therefore need to be laid down.

6. In order to achieve optimum protection of health, obsolete or repetitive tests will not be carried out, whether within the Community or in third countries. The harmonisation of technical requirements for the development of medicinal products should therefore be pursued through the appropriate fora, in particular the International Conference on Harmonisation.

(6) http://www.bmj.com/content/360/bmj.j5845

You can read this Press Release and our views in the Dutch language via https://www.gentechvrij.nl/bezwaren-2018/

Information:

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