Ter informatie een bericht aan Dr. Andriukaitis, European Commissioner for Health and Food Safety op 3 januari 2018 per e-mail over IM-MV 17-004, antwoord ontvangen op 17 januari 2018.

Staatssecretaris van IenW, Mevr. S. van Veldhoven

T.a.v. RIVM/VSP/Bureau GGO

Postbus 1

3720 BA Bilthoven

Lelystad, 17 januari 2018.

Geachte Staatssecretaris,

Te uwer informatie. Nog een extra bijlage en open brief.

Zijn betreffende de aanvraag met kenmerk IM-MV 17-004 de eerdere fases van de proef (gentech proeven op pasgeboren baby´s in Zuid-Afrika) uitgevoerd volgens de ethische principes van de Declaration of Helsinki?

Fragment van onderstaande brief die ik vandaag als bijlage per email ontving van Dr. Andriukaitis, European Commissioner for Health and Food Safety*:*

…….during the assessment of an application for the authorisation 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.

Hoogachtend,

Miep Bos, woordvoerster van De Gentechvrije Burgers (The European GMO-free Citizens), ook namens hen. Ook namens en in opdracht van Stichting Ekopark, Lelystad en Wieteke van Dort, Den Haag en anderen.

Lelystad
https://www.gentechvrij.nl/im-17-004-aanvulling/ (Onze zienswijze en open brief, drie aanvullingen en open brieven en deze extra bijlage en open brief zijn binnenkort ook via deze URL te vinden).

Hierna volgt eerst onze email van 3 januari 2018 aan Dr. Andriukaitis en daarna zijn antwoord van 17 januari 2018.

Ter informatie een bericht aan Dr. Andriukaitis, European Commissioner for Health and Food Safety op 3 januari 2018 per e-mail over IM-MV 17-004, antwoord ontvangen op 17 januari 2018.

Dear Dr. Andriukaitis,

First: Best Wishes For 2018!

Re: Medical Trails with GMOs

We as the European GMO-free Citizens have sent a view on the application of a medical trail with GMOs in the Antoni van Leeuwenhoek Hospital in Amsterdam, NL to the secretary of Environment (Ministerie van IenW).

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

Studies in newborn infants from Africa

In the SNIF we read: *VPM1002 (Hyg+)-specific human data are available from three clinical trials (3). Two studies in healthy adolescent volunteers and one phase IIa study in* ***healthy newborn infants*** *were performed. Combining the clinical safety data with the preclinical safety data, we conclude that VPM1002*

(Hyg+) is better than M. bovis BCG in terms of safety (see Part A section A5.1.)

The Application reads:

> 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 and Phase II double-blind, randomized, controlled study to evaluate the safety and immunogenicity of VPM1002 in
>
> comparison with BCG in HIV-exposed and HIV-unexposed, BCG-naive newborn infants.

So, before the GM trail in Amsterdam could take place, another GM study in African newborns has been performed! Although the mothers did give their consent for the trail, the question is, do they know it's an experimental trail? And on newborn children! How is it possible that newborns from Africa are used for such a GM research?

SNIF: http://gmoinfo.jrc.ec.europa.eu/bsnifs-gmo/B-NL-17-004.pdf

More info: http://www.ggo-vergunningverlening-zoeken.nl/

Ter informatie een bericht aan Dr. Andriukaitis, European Commissioner for Health and Food Safety op 3 januari 2018 per e-mail over IM-MV 17-004, antwoord ontvangen op 17 januari 2018.

Our view: https://www.gentechvrij.nl/wp-content/uploads/2017/12/IM-17-004-bezwaar-gmo-bacterieproef-Adam-z-adres.pdf Our follow up letter is still in progress.

I wanted you to know what is going on. Did you know? Is this ethic? How is it possible in this age that African children are guinea pigs?

Vriendelijke groet, Regards,

Mrs. Miep Bos, woordvoerster van de Gentechvrije Burgers, Europees Consumentenplatform.
(spokeswoman of The European GMO-free Citizens).

Lelystad

The Netherlands

www.gentechvrij.nl

Ter informatie een bericht aan Dr. Andriukaitis, European Commissioner for Health and Food Safety op 3 januari 2018 per e-mail over IM-MV 17-004, antwoord ontvangen op 17 januari 2018.

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medical products: quality, safety, innovation

Brussels,
sante.ddg1.b4/CA/ns (2018)

Dear Mrs. Miep Bos,

I am writing with respect to your email dated 3 January 2018 regarding Medical Trials with GMOs, to which Commissioner Andriukaitis asked me to reply.

Unfortunately, we do not have information on these clinical trials to reply to all your questions. Nevertheless, all clinical trials conducted in the European Union (EU) must comply with the provisions of Directive 2001/20/EC[1]. Moreover, during the assessment of an application for the authorisation 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.

I recommend that you follow-up any query in relation to a clinical trial with the relevant national authorities since the competence and responsibility for assessing and supervising the conduct of clinical trials lie with the Member States.

I wish you all the best for 2018.

Yours sincerely,

p.o.

Anna-Eva Ampelas
Head of Unit

Mrs. Miep Bos,
woordvoerster van de Gentechvrije Burgers, Europees Consumentenplatform.
(spokeswoman of The European GMO-free Citizens).
Donaustraat 170
8226 LC Lelystad
The Netherlands

[1] Directive 2001/20/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use

Elektronisch gedateerd 16-01-2018