Bioveiligheidsraad
Conseil de Biosécurité

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Secretariaat
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Advice of the Belgian Biosafety Advisory Council with regards to new information concerning notification B/BE/08/BVW1 of the company MedImmune for deliberate release in the environment of genetically modified organisms other than higher plants for research and development

Context

The notification B/BE/08/BVW1 has been submitted by MedImmune to the Belgian Competent Authority in October 2008 for a request of deliberate release in the environment of genetically modified organisms other than higher plants for research and development according to Chapter II of the Royal Decree of 21 February 2005.

The title of the notification is: **"A Phase 1/2a, Randomized, Double-Blind, Placebo-Controlled, Dose-Escalation Study to Evaluate the Safety, Tolerability, Immunogenicity and Vaccine-like Viral Shedding of MEDI-534, a Live, Attenuated Intranasal Vaccine Against Respiratory Syncytial Virus (RSV) and Parainfluenza Virus Type 3 (PIV3), in Healthy 6 to < 24 Month-Old Children and in 2 Month-Old Infants".** The planned activity concerns a clinical trial where the live, attenuated GM Bovine Parainfluenza virus (MEDI-534) will be administered as intranasal vaccine to healthy young infants for the prevention of lower respiratory tract illness caused by respiratory syncytial virus (RSV) and parainfluenza virus type 3 (PIV3). The purpose of the study is to evaluate the safety and immune response generated by administration of multiple doses of this vaccine in 2 groups of healthy infants : 6 to <24 month-old children and 2 month-old infants.

On 2 April 2009 the notifier was granted the authorisation from the Federal Minister to perform the trial on the conditions proposed by the Biosafety Advisory Council in its advice (advice of 12 February 2009 - ref. BAC_2009_889[1]).

On April 6th 2009 the notifier sent comments to the Competent authority about the conditions of the authorisation asking to reconsider a number of the conditions. This request was reviewed by the Council during its meeting of 21 April 2009 and its advice was sent to the competent authority on 23 April 2009 (ref. BAC_2009_927).

Concerning one of the conditions of the authorisation which is to '**perform a serological test of the parents before and after the study'** the notifier sent additional responses to the Belgium Biosafety Council on May 28th 2009. The arguments of the notifier were reviewed by the Council during its meeting of 15 june 2009.

[1] available at the following address: <http://www.bio-conseil.be/bac_advices.html>

The Biosafety Advisory Council accepts the arguments of the company:
- that the vast majority of people will have been routinely exposed to both RSV and PIV3 and thus be seropositive if tested;
- that if done in only one country the data collected will be of poor value.

In addition, the Council takes note that the company plans to evaluate the transmission profile of the vaccine as part of the overall product development plan and that this transmission study would be appropriately designed and powered to assess transmission in seronegative children.

For the above reasons the Biosafety Advisory Council considers that it is acceptable to suppress in the conditions of the authorisation the request to '**perform a serological test of the parents before and after the study**'.

p.o.

Prof. D. Reheul
President of the Belgian Biosafety Advisory Council

Wetenschappelijk Instituut Volksgezondheid | Institut Scientifique de Santé Publique
Afdeling Bioveiligheid en Biotechnologie | Section Biosécurité et Biotechnologie
Rue Juliette Wytsmanstraat 14 | B-1050 Brussels | Belgium
T + 32 2 642 52 11 | F + 32 2 642 52 92 | bac@sbb.ihe.be | www.bio-council.be