famhp
federal agency for medicines and health products

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Your letter from	Your reference	Our reference	Annex	Date
		FAGG/R&D/BEN	1	

Onderwerp
Titre de l'objet
Subject

Goedkeuring van een klinische proef op 11/10/2018
Approbation d'un essai clinique le 11/10/2018
Authorisation of a clinical trial dated 11/10/2018

A Phase 2, partial blind, randomized, placebo-controlled, multicenter study to evaluate the safety and immunogenicity of two novel live attenuated serotype 2 oral poliovirus vaccines candidates, in healthy adults previously vaccinated with oral polio vaccine (OPV) or inactivated polio vaccine (IPV), compared with historical controls given Sabin OPV2 or placebo.

EudraCT: 2018-001684-22

Cher Monsieur,

Conformément à l'article 12 de la Loi du 7 mai 2004 relative aux expérimentations sur la personne humaine, j'ai décidé d'autoriser l'essai clinique ci-dessus mentionné.

Cependant, un suivi doit être apporté aux points mentionnés en annexe.

Sincères salutations,

Pour la Ministre des Affaires sociales et de la Santé publique

Geachte Heer,

In overeenstemming met artikel 12 van de wet van 7 mei 2004 inzake experimenten op de menselijke persoon, heb ik besloten de hierboven vermelde proef goed te keuren.

Niettemin moet er gevolg gegeven worden aan de opmerkingen vermeld in bijlage.

Met de meeste hoogachting,

Voor de Minister van Sociale Zaken en Volksgezondheid

Dr. Greet Musch

Unofficial translation

In accordance with article 12 of the Law of 7 May 2004 concerning experiments on the human person, I have decided to authorise the above mentioned clinical trial. However, the points as mentioned in annex are to be followed up.

Annex

Regulatory

Please note that the FAMHP hereby approves the most recent version of the protocol (UAM4 version 2.1 dated 30/08/2018) which has been adapted by the Sponsor according to the conditions stated by the Biosafety Advisory Council in their advice of 10/08/2018.

Non-clinical

Recommendation

The sponsor is recommended to take into consideration the following recommendation during further development of the product. It may be readdressed at the time of assessment of future applications related to this investigational medicinal product:

According to the guidance "CTFG recommendations related to contraception and pregnancy testing in clinical trials" the risk of teratogenicity/ fetotoxicity based on the (absence of) non-clinical data is considered possible, and therefore highly effective birth control methods should be specified in the protocol. The applicant is referred to the this guidance document available at the HMA website: http://www.hma.eu/fileadmin/dateien/Human_Medicines/01-About_HMA/Working_Groups/CTFG/2014_09_HMA_CTFG_Contraception.pdf for definition of highly effective birth control methods.

Safety

Recommendation

The sponsor is recommended to take into consideration the following recommendation during further development of the product. It may be readdressed at the time of assessment of future applications related to this investigational medicinal product.

In view of the update of the CTFG - Q&A document on RSI (November 2017), published on: http://www.hma.eu/fileadmin/dateien/Human_Medicines/01-About_HMA/Working_Groups/CTFG/2017_11_CTFG_Question_and_Answer_on_Reference_Safety_Information_2017.pdf, the Sponsor should fully comply with the Q&A during the IB updates that follow this publication.

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Dossier OGM : B/BE/16/BVW2 (2018-001684-22): A Phase 2, double-blind, randomized, placebo-controlled, multicenter study to evaluate the safety and immunogenicity of two novel live attenuated serotype 2 oral poliovirus vaccines candidates, in healthy adults and adolescents previously vaccinated with oral polio vaccine (OPV) or inactivated polio vaccine (IPV), compared with historical controls given Sabin OPV2 or placebo.

Geachte Heer Van Damme,

Hierbij informeren wij u dat de vergunningsplicht krachtens het Koninklijk besluit van 21 februari 2005 tot reglementering van de doelbewuste introductie in het leefmilieu evenals van het in de handel brengen van genetisch gemodificeerde organismen of van producten die er bevatten u wordt toegekend op basis van het gunstig advies van de Adviesraad voor Bioveiligheid daterend van 10 augustus 2018 en dit volgens de voorwaarden hernomen in de conclusie van bovenvermeld advies, dat wil zeggen:

"The notifier and the investigators must strictly apply the clinical trial protocol, and all the exclusion/inclusion criteria and safety instructions as listed in Annex I.

- *Any protocol amendment has to be previously approved by the Competent Authority.*
- *The notifier is responsible to verify that each study centre has qualified personnel experienced in handling infectious material and that the investigator has the required authorizations to perform the clinical trial activities inside the hospital (laboratory, pharmacy, hospital room, consultation room...) according to the Regional Decrees transposing Directive 2009/41/EC on contained use of genetically modified micro-organisms.*
- *The Biosafety Advisory Council should be informed within two weeks when the first patient starts the treatment and the last patient receives the last treatment.*
- *At the latest six months after the last visit of the last patient included in the trial, the notifier must send to the competent authority at the attention of the Biosafety Advisory Council a report with details concerning the biosafety aspects of the project. This report will at least contain:*
    - *The total number of patients included in the trial and the number of patients included in Belgium;*

- *A summary of all adverse events marked by the investigators as probably or definitely related to the study medication;*
- *A report on the consequences, if any, of the of deliberate release of nOPV2 candidate vaccines."*

Met hoogachting,

Maggie De Block

Minister van Sociale Zaken en Volksgezondheid

Marie Christine Marghem

Minister van Energie, Leefmilieu en Duurzame Ontwikkeling