Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten
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DG PRE vergunning/afdeling Onderzoek en Ontwikkeling

[redacted]

AstriVax NV
[redacted]
Gaston Geenslaan 3
3001 Leuven

uw bericht van	uw kenmerk	ons kenmerk	bijlagen	datum
		FAGG/DGPRE/R&D/[redacted]		17.02.2025

Dossier GMO: B/BE/24/BVW6 (2024-518874-15-00): A randomised, double-blind, placebo-controlled, multi-centre, Phase I study to evaluate the safety, reactogenicity and immunogenicity of AstriVax' investigational therapeutic hepatitis B virus (HBV) vaccine (AVX70371) in adult patients with chronic HBV (CHB) infection

Geachte [redacted]

Wij informeren u dat uw vergunningsaanvraag werd goedgekeurd.

De vergunning is conform 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.
(http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=nl&la=N&cn=2005022131&table_name=wet)

Uw vergunning wordt verleend op basis van het gunstig advies van de Adviesraad voor Bioveiligheid van 23 januari 2025, onder de voorwaarden die in de conclusie van bovengenoemd advies zijn vermeld, namelijk:

"Based on the scientific assessment of the notification made by the Belgian experts, the Biosafety Advisory Council concludes that it is unlikely that PLLAV-YF17D/HBc developed as vaccine against hepatitis B virus, will have any adverse effects on human health on the environment in the context of the intended clinical trial, provided that all the foreseen safety measures are followed.

Therefore, the Biosafety Advisory Council issues a ***positive advice with the following conditions****:*

– The notifier and the investigators must strictly apply the clinical trial protocol and the safety instructions as described in the following documents :
- *o Latest version of the AVX37-101_ICF_ENG*
- *o Latest version of the AVX37-101_Protocol*
- *o LAV-YF17D_HBc_Instruction sheet for study personnel_v1.0 : Please make sure, the word "peronnel" in the title of the document has been corrected into "personnel".*
- *o LAV-YF17D_HBc_CAF_Public*
- *o LAV-YF17D_HBc_CAF_Confidential_Version 2.0_clean*
- *o LAV-YF17D_HBc _SNIF*

– Any protocol amendment has to be previously approved by the Competent Authority.

– As committed by the notifier, viraemia and shedding data of the AVX1248-101 trial with LAV-YF17D/RabG (EU CT number 2024-511194-29; notification number B/BE/23/BVW3) will be provided once available and analysed. Furthermore, the applicant is requested to take the necessary measures to protect health and

the environment if new information from this shedding analysis comes to light that may impact human health or environment.

– The notifier is responsible to verify that the study centre has qualified personnel experienced in handling infectious material and that the investigator has the required authorisations 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 the contained use of genetically modified micro-organisms.

– The BAC 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 the competent authority for the attention of the BAC a report with details concerning the biosafety aspects of the project. This report shall contain at least:

- *o The total number of patients included in the trial and the number of patients included in Belgium;*
- *o A summary of all adverse events marked by the investigators as probably or definitely related to the study medication;*
- *o A report on the accidental releases, if any, of PLLAV-YF17D/HBc."*

Hoogachtend,

Frank Vandenbroucke
Vice-eersteminister en
minister van Sociale Zaken en
Volksgezondheid, belast met
Armoedebestrijding

Jean-Luc Crucke
Minister van Mobiliteit,
Klimaat en Ecologische
Transitie