



Memorandum

DATE: September 18, 2023

TO: Sudhakar Agnihothram, Ph.D., Committee Chair
CBER/OVRR/DVRPA/OVRR

Konstantin Virnik, Ph.D. and Georgeta Crivat, Ph.D., RPMs
CBER/OVRR/DVRPA/CMC2

FROM: Alisa Gilliard, Pharm.D.
Consumer Safety Officer
CBER/OCBQ/DCM/APLB

Oluchi Elekwachi, Pharm.D., MPH
Program Coordinator
CBER/OCBQ/DCM/APLB

THROUGH: Lisa Stockbridge, Ph.D.
Branch Chief
CBER/OCBQ/DCM/APLB

SUBJECT: Labeling Review
IXCHIQ (chikungunya vaccine, live)
BLA 125777/0
Sponsor: Valneva Austria GmbH

Background:

The sponsor submitted:

New Approval
 Changes Being Effected (CBE) supplement
 Prior Approval Supplement (PAS) Amendment
 Major Amendment

Submission contains:

Prescribing Information (PI) – August 3, 2023 (Amendment 77)
 Patient Package Insert (PPI) – August 3, 2023 (Amendment 77)
 Package and/or container labels – August 3, 2023 (Amendment 77)
 Other

Submission Date: December 22, 2022
PDUFA Action Date: October 13, 2023

APLB Comments/Recommendations

On December 22, 2022, Valneva Austria GmbH completed its rolling submission for BLA 125777, IXCHIQ (chikungunya vaccine, live). IXCHIQ is indicated for active immunization against chikungunya virus in individuals 18 years of age and older. This indication is approved under accelerated approval based on anti-CHIKV neutralizing antibody titers. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). IXCHIQ is supplied in a carton containing a single-dose vial of lyophilized antigen component, live and a prefilled syringe of sterile water diluent component.

APLB participated in the IXCHIQ Review Team to iteratively negotiate revisions to the Prescribing Information (PI), Patient Package Insert (PPI), package and container labels through communications with the applicant. APLB reviewed the revised PI, PPI, package, and container labels dated August 3, 2023, and found them acceptable from a promotional and comprehension perspective. We offer the following comments for consideration.

GENERAL

Proofread the entire PI to ensure that

- there are no editorial errors,
- changes in the HIGHLIGHTS section are carried throughout the document, and
- cross-referencing is accurate.

HIGHLIGHTS (HL)

Consider rewording **DOSAGE FORMS AND STRENGTHS** for readability and comprehension. Ensure that this is section of the HL is consistent with the **FULL PRESCRIBING INFORMATION**. For example:

IXCHIQ is a solution for injection supplied as a single-dose vial of lyophilized antigen component to be reconstituted with the accompanying prefilled syringe of sterile water diluent component. A single dose after reconstitution is approximately 0.5 mL.

FULL PRESCRIBING INFORMATION CONTENTS

Ensure that the table of contents is consistent with the sections and subsections of the **FULL PRESCRIBING INFORMATION**.

FULL PRESCRIBING INFORMATION (FPI)

3 DOSAGE FORMS AND STRENGTHS

Consider revising to the following (see above):

IXCHIQ is a solution for injection supplied as a single-dose vial of lyophilized antigen component to be reconstituted with the accompanying prefilled syringe of sterile water diluent. After reconstitution and withdrawal, the syringe contains a single dose of approximately 0.5mL.

5 WARNINGS AND PRECAUTIONS

5.1 Preventing and Managing Allergic Reactions

Remove the second repeated word 'immediate'.

8 USE IN SPECIFIC POPULATONS

8.1 Pregnancy

- Use upper case 'D' in Human Data and Animal Data.
- Ensure cross reference sections and subsections are accurate.

12 CLINICAL PHARMACOLOGY

- Please note the exclusion of required subsection **12.2 Pharmacodynamics** and
- Renumber **Pharmacokinetics** to 12.3.

17 PATIENT COUNSELING INFORMATION

For readability, present this section in bulleted format.

PATIENT PACKAGE INSERT

Under “**What should I tell my health care professional before I am vaccinated with IXCHIQ?**”, consider revising as follows:

It is very important to tell your health care provider if you are:

- pregnant or planning to become pregnant.
- breast feeding or planning to begin breast feeding.

Under “**What are the possible side effects of IXCHIQ?**”, consider revising to consumer-friendly language.

If you have any questions regarding this review please contact Alisa Gilliard, Pharm.D. at 240-402-9202.
