MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan.

MHRA-100986-PIP01-23-M01

Scope of the Application

Active Substance(s)

ENCORAFENIB

Condition(s)

Treatment of melanoma

Pharmaceutical Form(s)

Capsule, hard

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Pierre Fabre Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Pierre Fabre Limited submitted to the licensing authority on 28/04/2023 15:19 BST an application for a Modification

The procedure started on 31/08/2023 09:41 BST

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to accept change(s) to the agreed paediatric investigation plan.

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-100986-PIP01-23-M01

Of 18/09/2023 14:14 BST

On the adopted decision for ENCORAFENIB (MHRA-100986-PIP01-23-M01) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan).

This decision applies to a Modification for ENCORAFENIB, Capsule, hard , ORAL USE .

This decision is addressed to Pierre Fabre Limited, 250 Longwater Avenue, Green Park, Reading, UNITED KINGDOM, RG2 6GP

ANNEX I

1. Waiver

1.1 Condition:

Treatment of melanoma The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 12 years of age. Pharmaceutical form(s): Capsule, Hard Route(s) of administration: ORAL USE Reason for granting waiver: On the grounds the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of melanoma

2.2 Indication(s) targeted by the PIP:

Encorafenib in combination with binimetinib is indicated for the treatment of patients aged 12 years and older with unresectable or metastatic melanoma with a BRAF V600 mutations.

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from 12 years to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Capsule, Hard

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Study 1 This study was deleted during procedure MHRA-100986-PIP01-23-M01.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	0	Study 2 This study was deleted during procedure MHRA-100986-PIP01-23-M01.
Extrapolation, Modeling & Simulation Studies	1	Study 3 (This study is the same as Study 3 in procedure MHRA-100985-PIP01-23-M01) Modelling and simulation study to evaluate and to determine the dose of encorafenib used in combination with binimetinib which matches adult plasma exposure and for the use of the products in the treatment of melanoma in adolescents from 12 to less than 18 years of age with unresectable or metastatic BRAF V600 mutant melanoma. Extrapolation Plan (This measure was added during procedure MHRA-100986-PIP01-23-M01) Study 3 is part of an extrapolation plan covering the paediatric population with unresectable or metastatic BRAF V600 mutant melanoma from 12 years to less than 18 years of age, as agreed by the Regulatory Agency .
Other Studies	0	Not applicable.
Other Measures	0	Not applicable.

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	31/01/2024
Deferral of one or more studies contained in the paediatric investigation plan:	No