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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

grant a product specific waiver

MHRA-100806-PIP01-22

Scope of the Application

Active Substance(s)

ALPELISIB

Condition(s)

Treatment of ovarian cancer (excluding rhabdomyosarcoma and germ cell tumours), Treatment of Fallopian cancer (excluding rhabdomyosarcoma and germ cell tumours), Treatment of Peritoneal cancer (excluding blastomas and sarcomas).

Pharmaceutical Form(s)

All pharmaceutical forms

Route(s) of Administration

All routes of administration

Name / Corporate name of the PIP applicant

Novartis Pharmaceuticals UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Novartis Pharmaceuticals UK Limited submitted to the licensing authority on 05/12/2022 11:07 GMT an application for a

The procedure started on 14/04/2023 17:40 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 grant a product specific waiver

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-100806-PIP01-22

Of 31/05/2023 11:42 BST

On the adopted decision for ALPELISIB (MHRA-100806-PIP01-22) in accordance with the Human Medicines Regulations 2012.

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

Granting a waiver in all age groups for the listed condition(s)

This decision applies to a for ALPELISIB, All pharmaceutical forms , ORAL USE .

This decision is addressed to Novartis Pharmaceuticals UK Limited, 2nd Floor, The WestWorks Building, White City Place, 195 Wood Lane, , London, UNITED KINGDOM, W12 7FQ

ANNEX I

1. Waiver

1.1 Condition:

Condition 1: Treatment of ovarian cancer (excluding rhabdomyosarcoma and germ cell tumours) Condition 2: Treatment of Fallopian cancer (excluding rhabdomyosarcoma and germ cell tumours) Condition 3: Treatment of Peritoneal cancer (excluding blastomas and sarcomas) For all three conditions, the waiver applies / applied to: Paediatric Subset(s): All subsets of the paediatric population from birth to less than 18 years of age Pharmaceutical form(s): All pharmaceutical forms Route(s) of administration: All routes of administration Reason for granting waiver: on the grounds that 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):

Not applicable

2.2 Indication(s) targeted by the PIP:

Not applicable

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

Not applicable

2.4 Pharmaceutical Form(s):

Not applicable

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures		
Non-Clinical Studies		
Clinical Studies		
Extrapolation, Modeling & Simulation Studies		
Other Studies		
Other Measures		

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

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	
Date of completion of the paediatric investigation plan:	
Deferral of one or more studies contained in the paediatric investigation plan:	