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 and to the deferral

MHRA-100158-PIP01-21-M01

Scope of the Application

Active Substance(s)

PEMBROLIZUMAB

Condition(s)

Treatment of Hodgkin lymphoma

Pharmaceutical Form(s)

Concentrate for solution for infusion; Powder for concentrate for solution

Route(s) of Administration

Intravenous use

Name / Corporate name of the PIP applicant

Merck Sharp & Dohme (UK) Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Merck Sharp & Dohme (UK) Ltd submitted to the licensing authority on 09/08/2021 13:53 BST an application for a Modification

The procedure started on 07/07/2022 14:04 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 and to the deferral

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-100158-PIP01-21-M01

Of 12/07/2022 07:34 BST

On the adopted decision for PEMBROLIZUMAB (MHRA-100158-PIP01-21-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 PEMBROLIZUMAB, Concentrate for solution for infusion; Powder for concentrate for solution for infusion , Intravenous use .

This decision is addressed to Merck Sharp & Dohme (UK) Ltd, 120 Moorgate, London, United Kingdom, EC2M 6UR

ANNEX I

1. Waiver

1.1 Condition:

Treatment of Hodgkin lymphoma The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 3 years of age Pharmaceutical form(s): Concentrate for solution for infusion; Powder for concentrate for solution for infusion Route(s) of administration: Intravenous use Reason for granting waiver: on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of Hodgkin lymphoma

2.2 Indication(s) targeted by the PIP:

Treatment of classical Hodgkin lymphoma with complete early response to front-line chemotherapy in children from 3 years to less than 18 years of age.; Treatment of relapsed or refractory classical Hodgkin lymphoma in children from 5 years to less than 18 years of age

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

The paediatric population from 3 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Concentrate for solution for infusion; Powder for concentrate for solution for infusion

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable
Non-Clinical Studies	0	Not applicable
Clinical Studies	2	Study 1: Multi-centre, open-label, single-arm trial to evaluate pharmacokinetics, pharmacodynamics, toxicity, safety and activity of pembrolizumab in paediatric patients from 6 months to less than 18 years with an advanced melanoma or a PD-L1 positive advanced, relapsed or refractory solid tumour or lymphoma, including an expansion phase (same as study 2 in EMEA-001474-PIP01-13) Study 2: Open-label, non-controlled trial to evaluate the safety and efficacy of pembrolizumab in combination with chemotherapy in paediatric patients from 3 years to less than 18 years of age (and young adults) with a classical Hodgkin with incomplete early response to front-line therapy
Extrapolation, Modeling & Simulation Studies	0	Not applicable
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:	31/03/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes