MERCK SHARP & DOHME (UK) LIMITED
120 MOORGATE
LONDON
EC2M 6UR
UNITED KINGDOM

06 November 2023

AMENDMENT

to

THE MARKETING AUTHORISATION

for

Name of the Medicinal Product		KEYTRUDA	
MAH		MERCK SHARP & DOHME (UK) LIMITED	
Active substance(s)		PEMBROLIZUMAB	
MA-no(s)	Pharmaceutical form(s)	PLGB 53095/0040	25 mg/mL concentrate for solution for infusion

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Referring to your letter of 04 October 2023 and to variation application procedure PLGB 53095/0040 - 0060 the Medicines and Healthcare Products Regulatory Agency confirms, under regulation 58A(2) of the Human Medicines Regulations 2012, as amended, that the following statement of compliance is included in the amendment of the marketing authorisation:

It has been verified that the application included the results of all studies performed covering existing and new indications, pharmaceutical forms and routes of administration in compliance with the agreed completed paediatric investigation plan. It is further confirmed that the Summary of Product Characteristics has been amended to reflect the results of studies conducted in compliance with the agreed paediatric investigation plan.

Compliance statement

The licensing authority is satisfied that the material provided by the applicant pursuant to regulation 50A(3) and Article 7 / 8 of Regulation No.1901/2006 demonstrates compliance with the agreed paediatric investigation plan EMEA-C-001474-PIP01-13-M01 (Decision number P/0043/2018).

The enclosed Summary of Product Characteristics reflects the results of the above-mentioned agreed paediatric investigation plan.

Yours sincerely,

MHRA