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

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-102245-PIP01-25

Scope of the Application

Active Substance(s)

matrix applied characterised autologous cultured chondrocytes

Condition(s)

Treatment of cartilage disorders

Pharmaceutical Form(s)

Implant

Route(s) of Administration

INTRA-ARTICULAR USE

Name / Corporate name of the PIP applicant

Vericel UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Vericel UK Limited submitted to the licensing authority on 18/12/2025 23:29 GMT an application for a Paediatric Investigation Plan

The procedure started on 09/01/2026 12:21 GMT

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 agree a paediatric investigation plan and grant a deferral and grant a 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-102245-PIP01-25

Of 18/05/2026 09:39 BST

On the adopted decision for matrix applied characterised autologous cultured chondrocytes (MHRA-102245-PIP01-25) 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 a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for matrix applied characterised autologous cultured chondrocytes, Implant , INTRA-ARTICULAR USE .

This decision is addressed to Vericel UK Limited, 8 Bishopsgate , London, UNITED KINGDOM, EC2N 4BQ

ANNEX I

1. Waiver

1.1 Condition:

Treatment of cartilage disorders The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 10 years of age Pharmaceutical form(s): Implant Route(s) of administration: INTRA-ARTICULAR USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of cartilage disorders

2.2 Indication(s) targeted by the PIP:

Treatment of symptomatic, single or multiple full-thickness cartilage defects of the knee with or without bone involvement

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

The paediatric population from 10 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Implant

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 1 (55-1702-1; PEAK) Randomised, active-controlled, open-label, parallel group trial to evaluate the efficacy and safety of matrix applied characterised autologous cultured chondrocytes (MACI) compared to arthroscopic microfracture in the treatment of patients from 10 years to less than 18#years of age with symptomatic articular chondral or osteochondral defects of the knee.
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:	No
Date of completion of the paediatric investigation plan:	31/12/2030
Deferral of one or more studies contained in the paediatric investigation plan:	Yes