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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the deferral

MHRA-102514-PIP01-26-M01

Scope of the Application

Active Substance(s)

Concentrate of proteolytic enzyme enriched in in bromelain

Condition(s)

Treatment of burns.

Pharmaceutical Form(s)

Powder and gel for gel

Route(s) of Administration

CUTANEOUS USE

Name / Corporate name of the PIP applicant

MediWound Germany GmbH

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, MediWound Germany GmbH submitted to the licensing authority on 14/05/2026 11:47 BST an application for a Modification

The procedure started on 02/06/2026 19:56 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.

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

gov.uk/mhra

Final Decision Letter

MHRA-102514-PIP01-26-M01

Of 17/06/2026 09:40 BST

On the adopted decision for Concentrate of proteolytic enzyme enriched in in bromelain (MHRA-102514-PIP01-26-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 Concentrate of proteolytic enzyme enriched in in bromelain, Powder and gel for gel , CUTANEOUS USE .

This decision is addressed to MediWound Germany GmbH, Hans-Sachs-Strasse 100, Rüsselsheim, GERMANY, 65428

ANNEX I

1. Waiver

1.1 Condition:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of burns.

2.2 Indication(s) targeted by the PIP:

Removal of eschar in deep partial and/or full thickness burns.

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

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

2.4 Pharmaceutical Form(s):

Powder and gel for gel

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable
Non-Clinical Studies	2	Study 1 (Protocol # 20002067) Single dose toxicity study of concentrate of proteolytic enzymes in bromelain powder administered intravenously to minipigs with a 14-day observation period. Study 2 14-Day repeated intravenous dose study in juvenile pigs with collection of toxicokinetic data.
Clinical Studies	2	Study 3 (MW2012-01-02) Multicentre trial to assess long-term scar formation and quality of life in adults and children from 4 to less than 18 years of age comparing debridement of burn wounds with concentrate of proteolytic enzymes in bromelain to standard of care. Study 4 (MW2012-01-01) Assessor-blinded, randomised, multicentre trial to evaluate pharmacokinetics, safety, efficacy and immunogenicity of concentrate of proteolytic enzymes in bromelain for debridement of partial thickness and full thickness thermal burns compared to standard of care in children from birth to less than 18 years of age. Study 5, deleted during procedure MHRA-102514-PIP01-26-M01.
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:	31/12/2022
Deferral of one or more studies contained in the paediatric investigation plan:	Yes