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-101262-PIP01-23-M01

Scope of the Application

Active Substance(s)

DIENOGEST; ETHINYLESTRADIOL

Condition(s)

Prevention of pregnancy

Pharmaceutical Form(s)

Prolonged-release tablet

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

EXELTIS HEALTHCARE S.L.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, EXELTIS HEALTHCARE S.L. submitted to the licensing authority on 16/11/2023 16:20 GMT an application for a Modification

The procedure started on 05/02/2024 12:27 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 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-101262-PIP01-23-M01

Of 09/02/2024 11:42 GMT

On the adopted decision for DIENOGEST; ETHINYLESTRADIOL (MHRA-101262-PIP01-23-M01) in accordance with the Human Medicines Regulations 2012.

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

AAgreement 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 DIENOGEST; ETHINYLESTRADIOL, Prolonged-release tablet , ORAL USE .

This decision is addressed to EXELTIS HEALTHCARE S.L., Avenida Miralcampo, 7 - Polígono Industrial Miralcampo, Azuqueca de Henares, Guadalajara, SPAIN, 19200

ANNEX I

1. Waiver

1.1 Condition:

Prevention of pregnancy The waiver applies / applied to: Paediatric Subset(s): Male paediatric population from birth to less than 18 years of age. Female paediatric population from birth to age at menarche. Pharmaceutical form(s): Prolonged-release tablet Route(s) of administration: ORAL USE Reason for granting waiver: On the grounds 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):

Prevention of pregnancy.

2.2 Indication(s) targeted by the PIP:

Prevention of pregnancy.

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

Female adolescents after age at menarche.

2.4 Pharmaceutical Form(s):

Prolonged-release tablet

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 Open-label, single arm, trial to evaluate safety, efficacy and pharmacokinetics of LPRI-424 (Dienogest 2.00 mg/ Ethinyl Estradiol 0.02 mg) in healthy female adolescents after menarche (and in adults) during 13 Cycles of 28 days.
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:	30/06/2023
Deferral of one or more studies contained in the paediatric investigation plan:	No