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

MHRA-101024-PIP01-23-M01

Scope of the Application

Active Substance(s)

gadoquatrane

Condition(s)

Diagnosis by evaluation of any known or suspected clinical condition with contrast enhanced magnetic resonance imaging

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

INTRAVENOUS

Name / Corporate name of the PIP applicant

Bayer plc

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Bayer plc submitted to the licensing authority on 24/05/2023 18:26 BST an application for a

The procedure started on 05/10/2023 10:03 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

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-101024-PIP01-23-M01

Of 16/10/2023 07:56 BST

On the adopted decision for gadoquatrane (MHRA-101024-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:

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 for gadoquatrane, Solution for injection , INTRAVENOUS USE .

This decision is addressed to Bayer plc, 400 South Oak Way, Reading, UNITED KINGDOM, RG2 6AD

ANNEX I

1. Waiver

1.1 Condition:

Diagnosis by evaluation of any known or suspected clinical condition with contrast enhanced magnetic resonance imaging The waiver applies / applied to: Paediatric Subset(s): Preterm newborn infants Pharmaceutical form(s): Solution for injection Route(s) of administration: INTRAVENOUS USE Reason for granting waiver: on the grounds that 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):

Diagnosis by evaluation of any known or suspected clinical condition with contrast enhanced magnetic resonance imaging

2.2 Indication(s) targeted by the PIP:

Contrast enhanced magnetic resonance tomography for the evaluation of suspected vasculature abnormalities, lesions or disease in any body region

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

The paediatric population from birth (infants born at term) to less than 18 years of age

2.4 Pharmaceutical Form(s):

Solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	2	Study 1 (TOXT103843-9) Extended single dose toxicity study in juvenile rats after intravenous administration with a following recovery period up to 4 weeks. Study 2 (T104292-8) Repeated dose toxicity study in juvenile rats after intravenous administration with a following recovery period up to 8 weeks.
Clinical Studies	1	Study 3 (21196) Study to evaluate the pharmacokinetics (PK) of BAY 1747846 in paediatric patients to support the extrapolation of efficacy from adults.
Extrapolation, Modeling & Simulation Studies	1	Study 4 (CPMX50059) Modelling and simulation study to evaluate the PK of BAY 1747846 in children from birth to less than 18 years of age and to extrapolate its efficacy for the diagnosis by evaluation with contrast enhanced magnetic resonance imaging from adults.
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:	30/06/2025

Deferral of one or more studies contained in the paediatric investigation plan:	No