Safeguarding public health



Dr M Barber NHS GREATER GLASGOW AND CLYDE TENNENT BUILDING, 38 CHURCH STREET WESTERN INFIRMARY GLASGOW G11 6NT UNITED KINGDOM

12/10/2012

Dear Dr M Barber

THE MEDICINES FOR HUMAN USE (CLINICAL TRIALS) REGULATIONS 2004 S.I. 2004/1031 (as amended)(the 'Regulations')

Our Reference:

24712/0025/001-0001

Eudract Number:

2012-002287-26

Product:

DURAPHAT DENTAL SUSPENSION 50MG/ML

Protocol number:

GN12CO201

ACKNOWLEDGEMENT OF NOTIFICATION

I am⁵ writing to confirm receipt of your notification of a clinical trial received on 11/10/2012.

For the purposes of regulation 18(2)(c) or 20(2)(a) and (5) of the Regulations (as appropriate), this letter is notice of authorisation of the trial referenced above with effect from 25/10/2012 (the 'effective date') subject to the following condition:

• that no further correspondence is received from the Licensing Authority before the effective date requiring full assessment of your request for authorisation.

You are reminded that your trial may be suspended or terminated at any time by the Licensing Authority in accordance with regulation 31. You must notify the Licensing Authority within 90 days of the trial ending.

Finally, you are reminded that a favourable opinion from the Ethics Committee is also required before this trial can proceed.

Yours sincerely,

Clinical Trials Unit MHRA