

FOI 23/759

Dear

Thank you for your email concerning ***diphenhydramine hydrochloride***.

According to our records diphenhydramine hydrochloride is not currently licensed in the UK for injection for local anaesthesia.

Please note that MHRA does not solicit applications for new medicines, or the addition of indications to current authorised medicines, and we do not conduct our own product development.

A company would need to approach us to apply for a Marketing Authorisation.

Sometimes there are clinical situations when the use of an unlicensed medicine or use of a medicine outside the terms of the licence (i.e., 'off-label') may be judged by the prescriber to be in the best interest of the patient on the basis of available evidence. Off-label use of a licensed medicine is the exclusive responsibility of the prescriber. We have published some information regarding off-label use on our website which you may find of interest. Please note that Healthcare professionals may have more responsibility to accurately prescribe an unlicensed medicine or an off-label medicine than when they prescribe a medicine within the terms of its licence: <https://www.gov.uk/drug-safety-update/off-label-or-unlicensed-use-of-medicines-prescribers-responsibilities>.

The General Medical Council (GMC) regulate doctors and how they prescribe. Guidance on off-label prescribing is provided by the [GMC](#).

Our role is to regulate medicines, medical devices, blood components for transfusion and to ensure that they are safe for the public to use in the UK. We do not provide medical advice and suggest you speak to your doctor or Healthcare professional on best treatment options.

We hope this is helpful.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information

Commissioner can be contacted at:

Information Commissioner's Office

Wycliffe House

Water Lane

Wilmslow

Cheshire

SK9 5AF

Yours sincerely

MHRA Customer Experience Centre

Communications and engagement team

Medicines and Healthcare products Regulatory Agency

10 South Colonnade, Canary Wharf, London E14 4PU