Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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MHRA Website

[redacted]

Our Ref: **FOI2026/00669**

16 July 2026

Dear [redacted]

Thank you for your Freedom of Information (FOI) request received on 22 June 2026. You wrote:

> *Could you please confirm whether PAR's are available for these products? If any of these PARs is not available, could you please advise under which authorisation route the product was approved, and what the reference product is?*
>
> - *PL 00142/0977, for which Accord is the MA holder*
> - *PL 15513/0157, for which McNeil is the MA holder*
> - *PL 20416/0535, for which Crescent Pharma Limited is the MA holder*
> - *PL 46302/0011, for which Mylan is the MA holder*
> - *PL 16028/0034, for which Galpharm is the MA holder*

MHRA Response
A marketing authorisation for Ibuprofen 100mg/5ml Oral Suspension (PL 00142/0977) was granted to Accord following a Change of Authorisation holder (CoA) on 17 July 2019. The original marketing authorisation for this product was granted to Actavis Group PTC EHF on 03 June 2015 following a decentralised procedure where the UK was Reference Member State (PL 30306/0514; UK/H/5608/001/DC). A link to the Public Assessment Report (PAR) is provided below:
https://mhraproducts4853.blob.core.windows.net/docs/ee7f36882635666d0f04f2a76f753ee8488f706b

Please note that PL15513/0157 has never been authorised in the UK. As no marketing authorisation has been granted for this, we will not be providing any further information.

A marketing authorisation for Orbis Ibuprofen For Children100mg/5ml Oral Suspension, Ibuprofen 100mg/5ml Oral Suspension (PL 20416/0535) was granted to Crescent Pharma Limited following a CoA on 15 July 2016. The original marketing authorisation for this product was granted to Orbis Consumer Products Limited on 13 November 2007 following an abridged simple "piggyback" application (PL 17862/0010). A link to the PAR is provided below:
https://mhraproducts4853.blob.core.windows.net/docs/7e6ae7be564f74f39062f216e6e1fe005d18f146

A marketing authorisation for Brufen Syrup (PL 46302/0011) was granted to Viatris Products Limited following a CoA on 09 September 2016. The original marketing authorisation for this product was granted to Knoll Pharma Limited on 01 April 1993 (PL 13530/0004). We hold no data on the original legal basis for this application. Because the original marketing authorisation was granted before it was a requirement for MHRA to publish PARs on our website, no PAR has been published or is available for this marketing authorisation.

A marketing authorisation for Junior Ibuprofen Suspension (PL 16028/0034) was granted to Galpharm Healthcare Limited on 07 April 1998. Because this marketing authorisation was granted before it was a requirement for MHRA to publish PARs on our website, no PAR has been published or is available for this marketing authorisation. The legal basis for this application was Article 4.8(a)(iii) of 65/65/EC, a generic application claiming essential similarity to Junifen Suspension (PL 00327/0077), which was authorised to Crookes Healthcare Limited on 11 August 1993.

Please note that the purpose of an FOI request is to confirm whether we hold information and consider that information for release, on request. We cannot advise on suitable reference products or requirements for applications through an FOI request. Please contact the Regulatory Information Service (RIS): RIS.NA@mhra.gov.uk, for information on suitable reference products and requirements for applications in the UK. Alternatively, you may wish to request a scientific advice meeting if you think this would be helpful. Further information on how to do this is available on our website:

Medicines: get scientific advice from the MHRA - GOV.UK

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113.

Re-use of our information
The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is