Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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MHRA Website

[redacted]

Our Ref: **FOI2025/00083**

20 February 2025

Dear [redacted]

Thank you for your Freedom of Information (FOI) request received on 30 January 2025. You wrote:

> *Can you please provide us with Public Assessment Reports for Paracetamol 120mg/5ml Oral Suspension, that have been submitted via the Article 10 (a) Well Established route. We have searched the MHRA database and have only managed to locate 4 PARs – 3 of which are for 10 (c) applications.*
>
> *Please find below PL numbers of the PARs we require:*
>
> *Boots - PL 00014/0638*
> *Crescent – PL20416/0521*
> *Galpharm – PL16028/0118 & 0119*
> *Haleon – PL44673/0088*
> *McNeil – PL15513/0300*
> *Pinewood – PL04917/0009 & 0028*
> *Rosemont – PL00427/0077*
> *Thornton & Ross – PL00240/0133"*

MHRA Response

Regarding the list you provided, please see our responses below concerning each product you have requested the Public Assessment Report (PAR) for.

- Infant Strawberry Pain Relief 120mg/5ml Suspension, Paediatric Paracetamol Oral 120mg/5ml Suspension (PL 00014/0638) was granted by a Change of Authorisation holder (CoA) to The Boots Company PLC on 18 September 2002. The original marketing authorisation was granted to BCM Limited on 27 November 2000 (PL 12557/0044) following the submission of an abridged standard (generic) application. As the original authorisation of this product predates when MHRA would have been required to prepare a PAR, no PAR has been published for this product.

- Paracetamol 120mg/5ml Oral Suspension (PL 20416/0521) was granted by a CoA to Crescent Pharma Limited on 24 May 2016. The original marketing authorisation was granted to Edict Consulting Limited on 03 March 2009 (PL 20941/0001) following the

submission of an abridged standard (generic) application. A link to this PAR is provided below:
https://mhraproducts4853.blob.core.windows.net/docs/d06fce77ee83c54fc7e210696a7fb7b9b8472a82

- Infant's & Children's Paracetamol Suspension (PL 16028/0118) was granted by a CoA to Galpharm Healthcare Limited on 08 October 2011. The original marketing authorisation was granted to Healthy Ideas Limited on 27 July 1995 (PL 10887/0002) following submission of an abridged standard (hybrid) application. As the original authorisation of this product predates when MHRA would have been required to prepare a PAR, no PAR has been published for this product.

- Panadol Baby and Infant Suspension (PL 44673/0088) was granted by a CoA to Haleon UK Trading Limited on 30 August 2016. The original marketing authorisation was granted to SmithKline Beecham (SWG) Limited on 10 October 1990 following submission of an abridged simple application (PL 00071/0355). As the original authorisation of this product predates when MHRA would have been required to prepare a PAR, no PAR has been published for this product.

- Calpol Sugar Free Suspension Infant (PL 15513/0300) was granted to McNeil Products Limited on 02 September 2009, following submission of an abridged simple application. A link to the PAR published on the MHRA website is provided below:
https://mhraproducts4853.blob.core.windows.net/docs/bae507ba0b5c25b6aa86b814bdca863dbd12607b

- Panaleve Suspension 2.4% w/v (PL04917/0009) was granted by a CoA to Pinewood Laboratories Limited on 10 September 1991 following submission of an abridged simple application. As the authorisation of this product predates when MHRA would have been required to prepare a PAR, no PAR has been published for this product.

- Paracetamol Suspension 120mg/5ml (PL 04917/0028) was granted to Pinewood Laboratories Limited on 25 May 1999 following submission of an abridged simple application. As the authorisation of this product predates when MHRA would have been required to prepare a PAR, no PAR has been published for this product.

- Paracetamol 120mg/5ml Oral Suspension (PL 00427/0077) was granted to Rosemont Pharmaceuticals Limited on 21 October 1986. As the authorisation of this product predates when MHRA would have been required to prepare a PAR, no PAR has been published for this product.

- Junior Paracetamol Suspension (PL 00240/0133) was granted by a CoA to Thorton and Ross Limited on 01 July 2004. The original marketing authorisation was granted to Galpharm Healthcare Limited on 05 January 1999 (PL 16028/0001) following submission of an abridged simple application. As the original authorisation of this product predates when MHRA would have been required to prepare a PAR, no PAR has been published for this product.

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.

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