Medicines & Healthcare products Regulatory Agency

[redacted]

MHRA Central Freedom of Information Team
10 South Colonnade
Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk.

MHRA Website

Our Ref: **FOI2025/00851**

9 September 2025

Dear [redacted]

Thank you for your Freedom of Information (FoI) request received on 13 August. You wrote:

> *Our company, [redacted] is developing a generic drug of Salbutamol Sulfate (dosage form: pressurised inhalation aerosol, 100μg). Pursuant to the requirements of MHRA's "Guideline on Reference Listed Drugs", we need to confirm the reference listed drug in the UK market. Upon initial search, Salamol CFC-Free Inhaler (IVAX, PL 00530/0555) was marketed in 2000, but its reference status is not clearly specified in the database.*
>
> *Please provide:*
> *1. Whether this medicinal product is listed as a reference listed drug in MHRA's registration files;*
> *2. The public assessment report.*
>
> *Product Information*
>
> *Name of the Medicinal Product Salamol CFC-Free Inhaler 100 micrograms Pressurised Inhalation, suspension.*
> *Pharmaceutical form Pressurised Inhalation, suspension*
> *Active Ingredient Salbutamol*
> *Marketing Authorisation Holder Norton Healthcare Ltd.,*
> *T/A IVAX Pharmaceuticals UK,*
> *Ridings Point,*
> *Whistler Drive,*
> *Castleford,*
> *West Yorkshire,*
> *WF10 5HX,*
> *United Kingdom*
> *Marketing Authorisation Number(s) PL 00530/0555*
> *Date of first authorisation 14 April 2000*

MHRA Response

We confirm that we hold some of the information you have requested, and we have provided this below.

Salamol CFC-Free Inhaler (PL 00530/0555) was authorised as an abridged application under the legal basis of EC Directive Article 4.8a(iii) (now Regulation 52B of the Human Medicines Regulation) and therefore, is not considered to be a suitable reference product.

The reference product listed on our case file for *Salamol CFC-Free Inhaler (PL 00530/0555)* is Ventolin Inhaler (PL 00045/5022R).

The requirement to produce a public assessment report (PAR) was introduced in 2005. The marketing authorisation for Salamol CFC-Free Inhaler (PL 00530/0555) pre-dates this requirement, so we do not hold a PAR 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.

Re-use of our information