

05/388 - Request

I read in a press release of the company Ivax (formerly Norton Healthcare in the UK) that they started marketing in the UK a fluticasone nasal spray product in May of this year. An NHS brochure states that the product is called Nasofan.

I tried to find the product on the lists of approved medicines but did not find it there. Could you please supply me the following information:

- Basic approval information (including if possible a copy of the SmPC)
- Information on the other EU Member States where the product received a marketing authorisation pursuant to the mutual recognition procedure
- If possible, information on how the equivalence (quality standards and bioequivalence) between this product and the reference product (Flixonase nasal spray) was determined.

Many thanks in advance.

Yours sincerely

[REDACTED]
By e-mail

Date 3 January 2006

Ref: FOI 05/388

Subject : Information on Nasofan

[REDACTED]
Thank you for your e-mail dated 6 December 2005, requesting information on Nasofan, specifically,

- Basic approval information (including if possible a copy of the SmPC)
- Information on the other EU Member States where the product received a marketing authorisation pursuant to the mutual recognition procedure
- If possible, information on how the equivalence (quality standards and bioequivalence) between this product and the reference product (Flixonase nasal spray) was determined.

This request is being considered under the Freedom of Information Act 2000.

The application for Nasofan Nasal Spray was submitted under Article 10.1(a)(iii) of EC Directive 2001/83, as amended, with a claim of essential similarity to Flixonase Nasal Spray (50mcg of fluticasone propionate) PL 10949/0036, which was granted to Glaxo Wellcome UK Limited on 15 September 1995 following a Change of Ownership from PL 00045/0153, which was granted on 8 March 1990. As with all medicinal products, Nasofan has been fully evaluated by the MHRA in relation to the appropriate standards required in the relevant European and National Rules and Regulations on Medicinal Products. Data in support of this application demonstrated that safety, quality and efficacy of the product was satisfactory for its intended use, and a UK Marketing Authorisation was granted on 12 May 2005. As requested, please find attached a copy of the current approved Summary of Product Characteristics for Nasofan.

Subsequent to the grant of the UK Marketing Authorisation, the MA holder, Ivax, requested that the UK act as Reference Member State in a Mutual Recognition Procedure. The procedure concluded on 27 October 2005 with the following Member States agreeing to the grant of a marketing authorisation: The Netherlands, Ireland, Spain, Denmark, Finland, Latvia, Lithuania, Poland, Italy, Czech Republic and Slovakia.

As previously mentioned, the application for Nasofan was submitted with a claim of essential similarity to Flixonase Nasal Spray under Article 10.1(a)(iii) of Directive 2001/83, as amended. From a regulatory perspective, at the time of submission of the Nasofan application, a medicinal product was defined as 'essentially similar' where it satisfied the criteria of having:

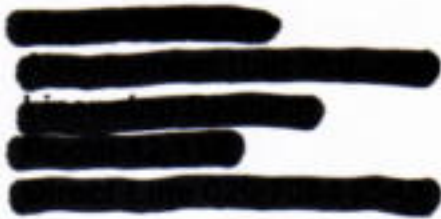
- The same qualitative and quantitative composition in terms of active principles
- The same pharmaceutical form
- And of being bioequivalent

unless it is apparent in the light of scientific knowledge that it differs significantly from the original product as regards safety or efficacy.

In this case, satisfactory data were submitted demonstrating essential similarity of the Ivax Nasofan product with the reference Flixonase product. This included a demonstration of the pharmaceutical equivalence of the two products in addition to the provision of a pharmacokinetic study comparing the bioavailability of Nasofan with Flixonase and a therapeutic equivalence study undertaken in patients and designed to investigate the safety and efficacy of Nasofan compared to Flixonase and placebo. The overall conclusion was that the benefit/risk profile of Ivax's Nasofan is acceptable and similar to that for Flixonase.

I hope the above information is helpful.

Yours sincerely,

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