

From: Tom Freyne <TomFreyne@scopeophthalmics.com>
Sent: 02 July 2012 23:36
To: SANCO FEES PHARMACOVIGILANCE
Cc: John Freyne
Subject: Concept paper on fees payable to EMA for pharmacovigilance

Importance: High

Attention: European Commission, DG Health and Consumers, Unit D5 'Medicinal products – authorisations, EMA'

To whom it may concern,

My name is Tom Freyne and I am a commercial director for an ophthalmic distribution company called Scope Ophthalmics.

We recently received your communication above from our Pharmacovigilance consultant. This document has shocked us greatly and has given us grave concerns about the future of our company.

Scope Ophthalmics is a small company, established in May 2009, that currently has no licensed products. We are planning to launch 4-5 medicinal products in the next year in the UK & Irish market. Some of these products are currently undergoing the review process with the MHRA and IMB, which means that we have already invested heavily in licensing some of these products.

The proposed fees will make any licensed medication for us totally impractical and unjustifiable. We would definitely not launch any medications in the UK & Irish market places if such fees were imposed.

Many of the products that we will launch are ophthalmic based preparations-which satisfy very niche needs.

I really hope that you can reconsider your proposal here and allow companies like Scope Ophthalmics to sell medicinal products in the UK & Ireland.

Yours sincerely,

Tom Freyne, Commercial Director

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Please see our new website; www.scopeophthalmics.com

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