

Auden Mackenzie Pharma Division (UK)

From: Vijayakumar Bathala <vijaya.bathala@audenmckenzie.com>
Sent: 14 September 2012 14:51
To: SANCO FEES PHARMACOVIGILANCE
Cc: Parag Patel
Subject: PC/12/05 - Public Consultation on pharmacovigilance fees

Importance: High

Hi,

Please find below the comments/ questions/ suggestions from a Private party – Auden Mckenzie (Pharma Division) Ltd.

Company name: Auden Mckenzie (Pharma Division) Ltd

Size: Medium enterprise

Consultation item no 1:

As 80,300 € is based on a Type II variation for a CAP product, the appropriate fee should also be based on the National Type II variation fees for a non-CAP product.

Consultation item no 2:

A fee of 80,300 € for generic products is disproportionate especially, as generic products are of a lower value than the innovators. Even with a 50 % reduction the cost is still excessive especially if there are only one or two generic manufacturers.

Clarification is sought on if the same active is available as a generic of one formulation and a generic of other formulation, is grouping still allowed?

Consultation item no 7:

The Pharmacovigilance fee of 1000 € per year per active is also excessive as generics already pay the national competent authority a yearly fee for each license.

[Should you require further information please do not hesitate to contact me.](#)

Kind Regards

Dr Vijayakumar Bathala
Pharmacovigilance officer

Auden Mckenzie (Pharma Division) Ltd.



Auden Mckenzie

Group

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