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.

Tel No: 01895 627 420
Fax No: 01895 631 777