

From: Patrick Salmon [Patrick.Salmon@imb.ie]
Sent: 31 January 2008 15:40
To: ARLETT Peter (ENTR)
Subject: Strategy to Better Public Health and Pharmacovigilance

----- Original Message -----

From: Patrick Salmon
To: 'peter.arlett@cec.eu.int' <peter.arlett@cec.eu.int>
Sent: Thu Jan 31 14:36:14 2008
Subject: Strategy to Better Public Health and Pharmacovigilance

Dear Dr Arlett

I have some brief comments in relation to proposed changes to the SmPC.

It seems strange to include the key safety information under section 3 pharmaceutical form rather than in section 4 clinical particulars. The section on the package leaflet proposes to include information after therapeutic indications.

It would be important to better define "key safety information" and to indicate who should decide what and how much information should be included in this section.

Best wishes

Patrick Salmon

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