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Received:	Sat, 26 Jan 2008 00:36:29 +0000
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content-transfer-encoding:	quoted-printable

From: Edwards, Roz

Sent: Wednesday, August 17, 2005 1:46 PM

To: Stribling, Don; Harrison, Ali; Malone, Hilary; Rogers, Anthony F (US); Tanaka, Michio; Pernvi, Christina; Readman, Ann S; Miller, Steven; Daniels, Moira; McKenna, Kevin; Smith, Pam; Milsted, Bob RAV (UK)

Cc: Cheeseman, Annie; Coney, Ken; Jonsson, Marianne; Kristoffersson, Katarina

Subject: FW: Format and content of Justification Documents

Attachments: Position Paper on JD production2.doc

Dear AZRALT,

Moira has asked me to forward this Position Paper to you in advance of our meeting on Monday 22/8. This will provide the background to the current situation on the format and content of safety Justification Documents.

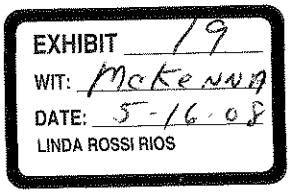
Kind regards,

Roz

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

From: Edwards, Roz

Sent: 02 August 2005 13:02



To: Smith, Pam

Cc: Daniels, Moira; McKenna, Kevin; Miller, Steven; Milsted, Bob RAV (UK)

Subject: Format and content of Justification Documents

Dear Pam,

We are writing to you in the first instance, as you may wish to discuss this with the other TA VPs at your forthcoming meeting on 22/23rd August.

Over the last 18 months, issues have arisen around the production of the post-SERM Justification Documents which have led the business to being out of compliance with regard to SOP timelines which state that JDs and Core Product Information documents should be dispatched to Marketing Companies no later than 10 weeks following SERM. This has been highlighted in a recent audit.

Since we took on our roles as Labelling Experts, we have been working closely with Drug Safety (continuing the work started by GPI) and we have had a notable success in agreeing with Drug Safety a new process over the ownership and review of the JDs which should help the current situation to some extent. However, the key issue around the appropriateness of the documentation still exists, in other words whether the JD is "fit for regulatory purpose" still exists.

We have prepared a position paper which summarises the current situation and suggests some potential solutions and we would be most grateful if you could read through this document and then we would wish to have a teleconference where we can seek assistance and advice from the TA VPs on defining a way forward to rectify this situation.

In summary the key issues are as follows:

The JDs which are currently being authored by Drug Safety require extensive editing before they are 'fit for regulatory purpose' - sometimes this editing is being done in-house, sometimes, unfortunately, we believe that this is being done by the marketing companies.

Additionally we are now supplying the markets with non-CTD compliant JDs which require further work in the marketing companies before they can be submitted.

We have been working closely with Muriel O'Byrne (acting RAD, GITA), Cecelia Potez (Director, EURA) and Janet Spiers-Alston (Global SERM Manager) to attempt to resolve some of these issues, and we have already succeeded in agreeing a new procedure for handling the JDs, whereby Drug Safety are now responsible for handling their review (previously the ownership of these documents was passed to and from Regulatory).

However, agreeing a template for the JDs is proving somewhat problematic, and this partly is because the JDs are now having to serve a 'medico-legal' purpose as well as a regulatory one, and also because the CTD format does not lend itself to the creation of a JD.

As we said, we would very much appreciate if you could read the attached document which explains the history and the current situation and if possible, we would like to arrange a teleconference with you and the other TA VPs to discuss the way forward.

Kind regards / Hälsningar

Annie, Katarina, Ken, Marianne and Roz