From: Kalsi, Gurdyal [Gurdyal.Kalsi@mdsinc.com]
Sent: 27 December 2007 01:51
To: ARLETT Peter (ENTR)
Subject: EC strategy to better protect public health by strengthening and rationalising EU PV - public consultation on proposals

Importance: High

Dear Peter,

The 5th Dec 2007 document is covering a critical agenda in that it intends to establish the central role of eudravigilance by improving the reporting, compliance, assessment and above all, a "rapid response" process.

The simplification of key definitions will help reduce variability connected with interpretation.

However, I hesistate to add that a major reporting burden stems from different views of Member States on adopted hazard criteria.

The suggested changes leave the criterion to be adopted for a triage leading to a eudravigilance report as yet not fully addressed or at least open to interpretation.

Suspected serious reports are destined for EV currently based on SUSAR criterion.

In some cases non SUSARs may be reported (i.e.,suspect serious "expected").

The strategy does not clarify the position on expectedness. Causality is well covered (reasonable probability or causality association cannot be excluded).

Harmonised assessment criterion agreed across member state CAs and allied stakeholders is one battle.

The other is mandating requirements for domestic and third country to be met via a common standard dictated by the committee and managed by it. The reporting timeframe is largely affected/impacted by patient awareness of the adopted criterion or timely identification of an ADR. The health professional's assessment of reported ADR is complicated by the stage of product characterisation. At times it is also affected by level of training (assessing causality) and time constraints.

Therefore strengthening activity ought to involve process simplification, unambigous language and a unified assessment approach/standard (suspect, unexpected and/or expected, serious AR) adopted by all.

One approach, one destination leading to one unified regulatory response.

PV system that tracks the identified/known hazard (via dynamic RMP) and reports to one agency database is as yet a dream (largely due to people related issues).

Best wishes and a happy New Year.

NB: is there a tracker that EC uses to capture variations (survey data) in country specific requirements for PV and Clinical Trial Applications?

Could you help with a copy or direct me to where I may find current information?

Regards

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(NB: We were together in the Dip Pharm Med course)