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Date: 04/18/2001 02:32:01 PM
From: CN=Jared G Kerr/OU=AM/O=LLY
Subject: South Africa Labeling Response: SmPC

John:

I hope all is well with you and you had a nice vacation. We recently received a request from our South Africa affiliate concerning the wording of hyperglycemia in their label. The CDS states:

Random plasma glucose levels ≥ 200 mg/dL (suggestive of potential diabetes) as well as random levels ≥ 160 mg/dL but < 200 mg/dL (suggestive of potential hyperglycemia) in patients with baseline random glucose levels ≤ 140 mg/dL have been seen occasionally in clinical trials.

The proposed comments from the South Africa MCC (MOH) is mostly from the SmPC section 4.4 "Special Warnings and special precautions for use".

Under "Warnings" - "Hyperglycemia or exacerbation of preexisting diabetes has been reported in very rare cases during ZYPREXA treatment. In some cases, a prior increase in body weight has been reported which may be a pre-disposing factor. Appropriate clinical monitoring is advisable in diabetic patients and in patients with risk factors for the development of diabetes mellitus." (South Africa MCC proposal)

Has the draft with the rappateur's comments on the SmPC specific to hyperglycemia been accepted and finalized? We need to determine our strategy regarding the South Africa MCC's proposal. Thanks.

Sincerely,

Jared Kerr, MPH

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