

Van: Mirela Pavic [Mirela.Pavic@pliva.com]

Verzonden: woensdag 24 augustus 2011 13:48

Aan: Gemert, mw. I. van; pchramsnl

CC: Marijana Cilas Krsic; Case Intern

Onderwerp: RE: REMINDER: case 149274 FW: REMINDER: NL/H/0945/001/II/008/G Azithromycin TEVA 200mg/5ml powder for oral suspension; End of procedure; case 197552

Dear Ms van Gemert,

Please note that this product in **not on the market** in the Netherland.

Please reply, would it be possible to send the mock-ups before the product will be introduced on the market?

Kind regards

Mirela

From: Gemert, mw. I. van [mailto:i.v.gemert@cbg-meb.nl]

Sent: Tuesday, August 23, 2011 12:34 PM

To: Mirela Pavic; pchramsnl

Cc: Marijana Cilas Krsic; Case Intern

Subject: RE: REMINDER: case 149274 FW: REMINDER: NL/H/0945/001/II/008/G Azithromycin TEVA 200mg/5ml powder for oral suspension; End of procedure; case 197552

Dear Ms Pavic,

Thank you for providing us with adapted texts for these procedures. The documents will be approved as attached. Kindly send in adapted mock-ups of the inner and outer package.

Kind regards,

Inge van Gemert

Medical Writer

Medicines Evaluation Board

Tel: 070 356 7434

Fax: 070 356 7515

E-mail: i.v.gemert@cbg-meb.nl

Van: Mirela Pavic [mailto:Mirela.Pavic@pliva.com]

Verzonden: donderdag 18 augustus 2011 11:40

Aan: Case; pchramsnl

CC: Marijana Cilas Krsic; Case Intern

Onderwerp: RE: REMINDER: case 149274 FW: REMINDER: NL/H/0945/001/II/008/G Azithromycin TEVA 200mg/5ml powder for oral suspension; End of procedure;

Dear Sir, Madam,

we are apologize for delay, but we have received updated national texts yesterday.

Please find enclosed national translations for implementation of NL/H/0945/001/II/008/G, NL/H/0945/001/IB/009 and NL/H/0945/001/IA/010 - clean and tracked SPC, PIL and LABEL. Please note that variations 008, 009, 010 are made in these texts.

NL/H/0945/001/II/008/G approved 09.05.2011.

NL/H/0945/001/IB/009 approved 17.03.2011.

NL/H/0945/001/IA/010 approved 08.08.2011.

Approval of variation NL/H/0945/001/IA/010 (Pliva Krakow as additional BTS/BRS) is enclosed in grouping variation NL/H/xxxx/IA/043/G, Case 218417. As explained in the cover letter for variation NL/H/xxxx/IA/043/G, updated PIL was not included in the variation package.

Kind regards

cid:image003.
jpg@01CBDEA0.3C12

Mirela Pavić, Senior Regulatory Affairs Specialist, Regulatory Affairs
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Mirela.Pavic@pliva.com | www.pliva.com

cid:image004.
jpg@01CBDEA0.

cid:image005.
cid:image006.

From: case@cbg-meb.nl [mailto:case@cbg-meb.nl]
Sent: Tuesday, August 16, 2011 3:23 PM
To: Mirela Pavic; pchramsnl
Cc: Marijana Cilas Krsic; CaseIntern@cbg-meb.nl
Subject: REMINDER: case 149274 FW: REMINDER: NL/H/0945/001/II/008/G Azithromycin TEVA 200mg/5ml powder for oral suspension; End of procedure;

Dear Sir, Madam,

Kindly be reminded of the below message and provide us with national translations for implementation of NL/H/0945/001/II/008/G. Please take into account that the adaptations required for variation NL/H/0945/001/IB/009 should be included in the NL texts as well.

On behalf of the
Medicines Evaluation Board

Dear Colleagues,
Last Saturday was D90 of the above mentioned procedure. Endorsement messages were received from PL and IE. Please find attached the final SPC, PL and labelling.
The applicant is asked to send documents for the national implementation within the agreed period.
Best regards,
Mr. L. Bongers, M.Sc.
Regulatory Project Leader (FT-3)
CBG-MEB
' +31 (0)70 356 7058
* l.bongers@cbg-meb.nl

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