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Your ref.
Date 14Mar2012

Applicant/MAH Name	Astellas Pharma Europe B.V.					
Customer Account Number	600120					
Customer Reference / Purchase Order Number						
Product Name	Qutenza					
Procedure Number	EMA/H/C/909/II/020					
INN / Active substance	Capsaicin					
Submission Type	Supplemental-info		**P**	□	**Q**	□
Description of Submission	Withdrawal of type II variation, consolidation sequence					
eCTD sequence	0065	**Related sequence**	0051, 0052, 0060			
Contact Persons' details (include email address)	**A) Regarding the content of the submission:** Name: Raymond van Aarle Telephone: +31 71 545 5909 E-Mail: Raymond.vanAarle @eu.astellas.com **B) Regarding technical questions:** Name: Ron de Boer Telephone: +31 71 545 5946 E-Mail: ron.deboer@eu.astellas.com **C) Regarding financial queries:** Name: Raymond van Aarle Telephone: +31 71 545 5909 E-Mail: Raymond.vanAarle@eu.astellas.com					

Dear Members of the CHMP,

I would like to inform you that, at this point in time, Astellas Pharma Europe B.V. has taken the decision to withdraw the variation application for a change to the marketing authorization for Qutenza Cutaneous Patch 179mg, a change in the Product Information submitted in May 2011 (#0020, sequence 0051), related to the exclusion of diabetics in the indication.

This withdrawal is based on the following reason:

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Astellas has taken this decision based on the CHMP's view that the data provided do not allow the Committee to conclude on a positive benefit risk balance.

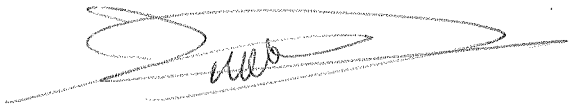
We reserve the right to make further submissions at a future date in this or other therapeutic indication(s), if applicable.

We agree for this letter to be published on the EMA website.

This letter is submitted as a consolidation sequence in line with 3.10 of the "eCTD Variations Q&A document". Documents are deleted from the eCTD as appropriate, submitted documents added to the eCTD for module 5 during the variation procedure, remain included (5.3.5.3 from sequence 0051; 5.4 from sequence 0060). The Product Information (1.3.1), Information about the Experts (1.4.3) and the Risk Management Plan (1.8.2) are not deleted or replaced with this consolidation sequence. These 3 documents were recently submitted in a new type II variation (Variation #0024, sequence 0064), both PI and RMP are based on current approved versions.

The enclosed CD-ROM has been scanned for viruses by state-of-the-art software (refer to the label for details).

Yours faithfully,
Astellas Pharma Europe B.V.



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Cc Rapporteur: Prof. Beatriz da Silva Lima
Co-Rapporteur : Prof. János Borvendég
Other CHMP Members