EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 January 2010
EMA/72240/2008

Request for confirmation of the applicability of the Agency's decision on class waivers

Background information on the product

	Please provide information in this column
Name (or corporate name) of applicant	
Address of applicant	
Name of contact person	
Email address of contact person	
Telephone number of contact person	
Name of active substance	
Invented name (If available)	
Type of product	
Class (condition) waiver you are referring to	
Date of the Agency's decision on class waiver	
Proposed or authorised indication(s) in adults (For authorised products, please provide the exact authorised indication(s) as stated in the latest SmPC.)	
Therapeutic area	

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E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Mechanism of action / target:

(Please provide a brief summary on the mechanism of action and the target.)

<Text>

<Text>

<Text>

Applicability of the published class waiver(s) to your indication(s):

(Please provide a short justification. This could include references to literature and/or disease classifications if available.)

<Text>

<Text>

<Text>

Potential use of the product in areas other than the proposed condition:

(If available, please provide a short summary on any potential or experimental use of your product in other therapeutic areas (paediatric or not) you are aware of, or are planning to investigate.)

<Text>

<Text>

<Text>