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CONFIDENTIAL

To Whom It May Concern

Re:

Dear Sir, Madam

Applicant / MAH Name	Shire Pharmaceutical Contracts Limited
Product Invented Name(s) & Strength(s)	
Type of Submission	
Description of Submission	
Submission Identifier	
Submission Date	
ATC Code	
INN / Name of Active Substance	

The proposed indication for Venvanse is as follows:

- Venvanse is indicated as part of a comprehensive treatment programme for attention deficit/hyperactivity disorder (ADHD) i

Notes to Reviewer:

(1)

(2) To aid navigation, a full Table of Contents for Module 1 is attached to this cover letter.

(3)

(4) The submission is provided in eCTD format and has been assembled in compliance with version 1.4 of the EU Regional Module 1 Specification and ICH v3.2 for Modules 2-5.

(5)

(6) Modules 3 and 5 of this dossier contain legacy reports which exceed the 100MB limit as advised in the guidance on EU Region eCTD Validation Criteria (version 3.0 – Jan 2011). The report numbers, locations and sizes are provided in the following table:

Module No.
3
5

Should you have any questions regarding this submission, please do not hesitate to contact the undersigned or

Yours faithfully

