



Joanna Wood
Independent Medicines and Medical Devices Safety Review
King's College, London
Shepherd's House
Room 3.25b
London SE1 1UL

10th July 2019

Dear Ms Wood,

We refer to your letter dated 1st July 2019, attaching extracts from a transcript of the evidence given to the Review on 22nd May 2019, by representatives of the Organisation for Anti-Convulsant Syndrome (OACS) and the Organisation for Anti-Convulsant Syndrome Ireland (OACS Ireland). You say, in your letter, that you wish to give Sanofi an opportunity to respond to certain specific criticisms of the company, made by OACS and OACS Ireland during their evidence, before this is published by the Review.

While Sanofi is sympathetic to OACS and OACS Ireland, we strongly object to the criticisms expressed in their evidence and believe that these are incorrect and based on a misunderstanding of both the factual history and the regulatory framework applicable at material times.

As you know, Sanofi has co-operated fully with the Review throughout this process. In particular, we consider that Sanofi has already addressed all of the issues raised by OACS and OACS Ireland in the very extensive written and oral evidence we have previously provided to the Review and that repeating such submissions in response to evidence given by individual witnesses would not be appropriate or helpful.

Sanofi remain willing to provide assistance to the Review where necessary.

Yours sincerely,

Henry Featherstone
Public Affairs Director
Sanofi UK