

14 May 2020

Michelle O'Neill MLA  
Deputy First Minister  
Coalition Sinn Féin Office  
Co Tyrone BT71 4LN

Dear Ms O'Neill,

Thank you for your letter to David Haslam dated 8 January 2020. Please accept my sincere apologies for the delay in responding. This is partly due to staff turnover and partly because David Haslam has retired as the Chair of NICE (Tim Irish is the interim Chair).

You ask two questions referring to a letter you received from Professor David Healy regarding the inquest into the death of Stephen O'Neill:

1. Is Professor Healy right in relation to clinical trials and related literature about on patent drugs, his assertion being 'that pretty well the entire literature on drugs like sertraline is ghost-written, that there is no access to the clinical trial data behind these articles, and that not even MHRA have effective access to the full dataset'? and,
2. If so, what in your opinion can be done in this area to make medical care safer for patients?

The issue of unpublished evidence is a challenge for anyone using evidence to inform treatment options. Researchers are expected to follow the Good Publication Practice guidelines, which includes medical writers being named in the acknowledgements of papers. Since 2016, the EMA has made all clinical data submitted to them for the marketing authorisation applications of new medicines available through a dedicated website (<https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/clinical-data-publication>). This means that all clinical data that was used by regulators is accessible to everyone within 60 days of marketing authorisation (after registering for access to the database), whether or not it has been published.

Of course, these procedures were not in place when most Selective Serotonin Reuptake inhibitor (SSRI), such as sertraline, were approved, but post-marketing surveillance can trigger regulatory action and the EMA completed a referral procedure on SSRIs and suicide in 2005:

<https://www.ema.europa.eu/en/medicines/human/referrals/serotonin-specific-reuptake-inhibitors-serotonin-noradrenaline-reuptake-inhibitors>

The authors of our Depression in Children guideline drew attention to the problems caused by unpublished evidence some years ago. Since this guideline was published, there has

been some progress in addressing the issue of unpublished evidence and positive bias in the published literature. In previous correspondence with Professor Healy on this subject, we have agreed with his view that it is not NICE's role to 'police' the academic literature, but we take the matter seriously and we are a signatory to the All Trials campaign which calls for all past and present clinical trials to be registered and their full methods and summary results reported.

Yours sincerely,

A handwritten signature in blue ink, appearing to read 'Gill Leng', with a stylized underline.

**Professor Gillian Leng CBE**

Chief Executive

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