

**Caroline Topping
HM Coroner's Court
Station Approach
Woking
Surrey
GU22 7AP**

14th August 2024

Dear Caroline Topping

We write in response to your letter to [REDACTED], Chief Executive Officer of the Royal Pharmaceutical Society, dated 26th July 2024 (Regulation 28 Report - Action to Prevent Future Deaths - Jessica Maizy Anne De Souza). Your letter was forwarded to us as the Publisher of the British National Formulary (BNF). We are sorry to hear the sad circumstances surrounding this case.

We have considered the matters of concern highlighted in your report that directly reference BNF (point ii), and additional concerns that do not specify the publication (points v and vi).

The matter of concern that directly references the BNF states that the clinicians relied on the BNF (and the BMJ Best Practice Bipolar Disorder in Adults) to support their decision to prescribe aripiprazole as prophylaxis for both polarities as a monotherapy. In Summer 2022, when aripiprazole was first prescribed to Ms De Souza, the aripiprazole drug monograph in BNF included one indication that was relevant to the management of bipolar disorder – that is the treatment and recurrence prevention of mania. The indication reflected, and continues to reflect, the licensed use of oral aripiprazole in licensed product information and is unchanged in current BNF content. The BNF does not include information on the use of aripiprazole as prophylaxis for bipolar depression.

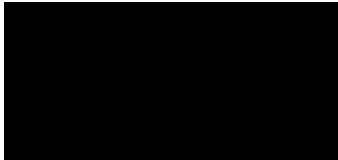
With regards to the matters of concern that do not specify the publication, it may be helpful to provide some context around the scope of the BNF. The BNF is designed as a digest for rapid reference for non-specialist health professionals, and it may not always include all the information necessary for prescribing and dispensing. The BNF should be interpreted in the light of professional knowledge and supplemented as necessary by specialised publications and by reference to the product literature. In Summer 2022, the BNF provided, and continues to provide, a general overview of the management of mania and hypomania in the *Mania and hypomania* treatment summary, with the recommendation that patients with suspected bipolar disorder should be referred to a specialist mental health service and treatment initiated on specialist advice. The treatment summary also advised, and continues to advise, that an antidepressant drug may also be required for the treatment of co-existing bipolar depression, along with brief information on when to avoid the use of an antidepressant. As noted above, the BNF does not include information on the use of aripiprazole as prophylaxis in relation to the depressive polarity in bipolar disorder, and as such, we do not consider that the guidance in the BNF may have been misleading for the clinicians.

As we do for all BNF content, we will continue to monitor for additional sources of information around the management of bipolar disorder, and consider whether we need to include further

information, at a level of detail that is appropriate to the scope of the BNF, for a future update of the BNF.

We trust that this addresses this important issue

Yours sincerely,



Content Director (BNF Publications)

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