

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

27 May 2021

Dear Ms Topping,

Re: Regulation 28 – Ann Coles

Issued: 13 April 2021
Received: 13 April 2021
Responded: 27 May 2021

Thank you for sending your Section 28 notice to the President of the Royal College of Physicians. This reply is on behalf of the organisation following consultation with appropriate officers and partners. In particular we have consulted with three experts in the British Cardiovascular Society and British Heart Rhythm Society.

Summary of response

Having reviewed the detail, the RCP would recommend that no new systems of monitoring and reporting are required for the prescription of amiodarone but that strict adherence to existing national NICE and local shared care guidelines will provide for safe and monitored practice.

Details of Response

Matters of Concern

"The evidence showed that a potential side effect of amiodarone medication is that it can cause toxicity which affects the lungs and can cause fibrotic changes. In her evidence the consultant cardiologist who treated Ann in her final illness raised the concern that there is no requirement for lung imaging to be undertaken when patients are prescribed amiodarone on a long-term basis which in her view was a glaring gap in the oversight necessary for the effects of the medication".

Pulmonary toxicity is a well-recognised side effect of amiodarone and it is considered to be "common" in the British National Formulary. Guidance in October 2020, from the National Institute for Health and Care Excellence (NICE), **Amiodarone – not initiated in primary care**¹ is clear that this drug should have **limited indications and reasserts how it should be initiated and then monitored.**

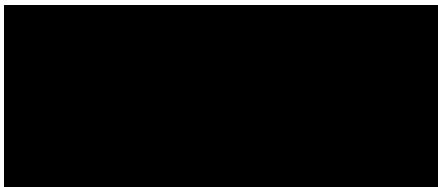
Before starting treatment, patients should have a chest x-ray but there is no requirement for routine pulmonary monitoring thereafter. The emphasis is one of ongoing drug review and if pulmonary toxicity is suspected then immediate specialist review. The focus should be on shared care guidelines agreed between local hospital trusts and their primary care clinical commissioning groups.

The RCP recommends adherence to such shared care guidelines and that arrangements for review of medications are in line with the recent NICE guidance (link below).

<https://cks.nice.org.uk/topics/atrial-fibrillation/prescribing-information/amiodarone-not-initiated-in-primary-care/>

We hope that these recommended actions will help prevent future problems of this nature.

Yours Sincerely,



Dr [REDACTED]
Registrar, Royal College of Physicians