

**Ms Alison Mutch**  
HM Senior Coroner  
Manchester South Coroner's Court  
1 Mount Tabor Street  
Stockport  
SK1 3AG

**National Medical Director**  
NHS England  
Wellington House  
133-155 Waterloo Road  
London  
SE1 8UG

05/08/2024

Dear Coroner,

**Re: Regulation 28 Report to Prevent Future Deaths – Linda McLaughlin who died on 27 October 2023**

Thank you for your Report to Prevent Future Deaths (hereafter "Report") dated 13 June 2024 concerning the death of Linda McLaughlin on 27 October 2023. In advance of responding to the specific concerns raised in your Report, I would like to express my deep condolences to Linda's family and loved ones. NHS England are keen to assure the family and the Coroner that the concerns raised about Linda's care have been listened to and reflected upon.

Your Report raises the concern that it is not widely known by healthcare professionals that interstitial lung disease is a rare side effect of treatment with a tyrosine kinase inhibitor drug called nilotinib, and that the consenting process for such a drug would not usually include mentioning such rare complications.

Your concerns and the circumstances of Linda's care have been shared with specialist Patient Safety and Cancer colleagues at NHS England. It is noted that interstitial lung disease is listed in the [Summary of product characteristics](#) for nilotinib as an uncommon respiratory side effect (see section 4.8) and the British National Formulary (BNF), which provides key information on the selection, prescribing, dispensing and administration of medicines for healthcare professionals, also lists respiratory disorders as an [uncommon side effect of the drug](#). The [Patient Information Leaflet](#) also makes mention of lung disorders as possible (uncommon) side effects, including "signs of interstitial lung disease: cough, difficulty breathing, painful breathing", so this information should have been available to the prescribers and the patient.

It is, however, acknowledged that the list of potential side effects is quite long, and it is unlikely that an uncommon complication such as this would normally be discussed when obtaining a patient's consent. It is a matter of individual clinical judgement about how extensive a discussion of potential but uncommon side effects should be. It would be expected that any patient developing respiratory symptoms while taking nilotinib would normally undergo rapid investigation and sometimes temporary cessation of the nilotinib treatment.

It should be noted that NHS England does not administer the BNF, and that regulation of medication does not sit within our remit. You may wish to revert to the BNF and/or

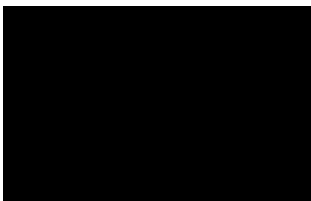
the Medicines & Healthcare products Regulatory Agency (MHRA), as the regulator of medicines used in the UK, who would be more appropriate to respond to your concerns on this matter.

Your Report also raises that there is growing evidence that some people do not need to stay on tyrosine kinase inhibitor drugs for life once in remission, but that there is no clear guidance on this and that consequently patients may remain on the drug longer than necessary. Again, you may wish to direct this concern to the MHRA who would be more appropriate to comment. However, specialist cancer colleagues have advised that this is an issue that currently remains in evolution. A proportion of patients can stop taking the drugs once they achieve a durable molecular remission, and this is normally discussed with patients after a certain length of time, weighing the potential toxicity of ongoing treatment against the risk of recurrence. The British Society for Haematology has an extensive guideline addressing this issue.

I would also like to provide further assurances on the national NHS England work taking place around the Reports to Prevent Future Deaths. All reports received are discussed by the Regulation 28 Working Group, comprising Regional Medical Directors, and other clinical and quality colleagues from across the regions. This ensures that key learnings and insights around events, such as the sad death of Linda, are shared across the NHS at both a national and regional level, and helps us to pay close attention to any emerging trends that may require further review and action.

Thank you for bringing these important patient safety issues to my attention and please do not hesitate to contact me should you need any further information.

Yours sincerely,



National Medical Director