Draft suggested letter to patients regarding paclitaxel V4 040619

Dear Sir/Madam,

We are writing to you as you have received a treatment to improve blood flow which involved the use of a drug called Paclitaxel. This drug was either coating a balloon which was opened in your artery or was incorporated into a stent, which releases the drug over time. The drug reduces the speed at which cells grow inside the vessel causing it to narrow or block again in the future. The use of these devices was approved at the time of your treatment and the evidence suggested that this drug ensured that your artery stayed open for longer and that the drug was safe.

Since your treatment evidence has come to light which has led to some safety concerns. This evidence suggests that the use of this drug may be associated with a small increased risk of death over a 2-5 year period. It is unclear what the cause for this is and urgent research is underway to understand it. It cannot at present be known for sure whether the use of this drug has or will in the future cause you any harm and there is no known way of reducing any risk to you. As a precaution the Medicines and Healthcare products Regulatory Agency have acted to limit the future use of this drug in routine clinical care, until more is known on this issue.

For the time being no specific additional tests or follow up is required apart from what you had been advised following the treatment.

We are deeply sorry for this situation and realise that this information may be difficult to accept and process, but we wish to reaffirm that the use of this technology was undertaken with your best interests in mind and was based upon the most up to date information available at the time. When further information becomes available to us we will write to you again.

If you would like to discuss this matter further over the phone or in person then please could you contact us via the attached contact information.