News story: Expert Advisory Group set-up to review paclitaxel drug-coated balloon catheters and drug-eluting stents

Following recently published findings by Katsanos et al raising concerns over the use of paclitaxel eluting balloons and stents in the treatment of patients with peripheral arterial disease (PAD) and in particular the femoropopliteal artery in the leg.

We have formed an independent Expert Advisory Group (EAG). The EAG has begun the process of reviewing the available, but highly complex information on these medical devices. The group is made up of leading UK clinicians from specialist societies, including interventional radiology, vascular surgery and scientists with toxicology, medicines and statistical expertise.

The publication suggests a possible increased mortality rate from 2 up to 5 years in PAD patients treated with paclitaxel-coated balloons and paclitaxel-eluting stents. This is compared to patients treated with non-coated balloons or bare metal stents. A causal relationship for this observation has not been identified and may reflect limitations in the way the data were analysed, but this has yet to be determined.

Patient safety is our highest priority and we take information questioning the safety of any medical device very seriously. Since the publication we have been collecting and analysing information from a range of sources to try to understand the significance of the findings for future patient treatment options.

The devices in question have valid CE certificates and remain on the UK market. The outcome of our investigation will determine if new advice is required or if we need to undertake any other regulatory action.

The EAG has been asked to consider whether the publication's findings and device-specific clinical study results are statistically robust and whether there is any evidence of a causal relationship between the drug, paclitaxel, and increased mortality.

There are a number of other publications which put forward different results and opinions taking into account other factors such as the the overall health of the patient.

To assist them they have been provided with the full spectrum of source material available to MHRA, together with all relevant published information we have gathered. The aim is to provide a greater understanding of the potential benefits and risks to patients and will help to guide any possible future MHRA action. The EAG has agreed to undertake and complete their

review, including reporting their findings to MHRA, within the next few months.

Additionally, we are collaborating with the major clinical and regulatory stakeholders, including the British Society of Interventional Radiology (BSIR), the UK Basil-3 trial and NICE, as well as other European and global regulatory authorities.

If you are worried that you might be affected by this matter, we advise you to contact your GP or specialist.