Medical Device Sector
Surveillance & Biometrics Executive Department

قطاع الأجهزة والمنتجات الطبية
الإدارة التنفيذية للرقابة والقياسات الحيوية

Safety Communication رسالة سلامة

Recommendations for using paclitaxel-coated devices in patients with intermittent claudication and critical limb ischaemia

Device/ Product Description:	paclitaxel-coated devices
Recommendations for the clinicians :	Based on an international regulatory authority report regarding using paclitaxel-coated devices in patients with intermittent claudication and critical limb ischaemia, you may consider the following: 1. Do not use paclitaxel drug-coated balloons (DCBs) or drug-eluting stents (DESs) in the routine treatment of patients with intermittent claudication, as the potential mortality risk generally outweighs the benefits. 2. In patients with critical limb ischaemia, management should follow that outlined in the NICE guideline on Peripheral arterial disease: diagnosis and management (CG147). 3. Use of paclitaxel DCBs and DESs in patients with critical limb ischaemia remains an option in selected cases, where the benefits may outweigh the risks. This is because such patients generally have a higher risk of irreversible ischemic damage should restenosis occur, which may lead to limb loss and a lower life expectancy. Decisions on whether to use these devices should be made through shared decision-making between the patient, their family and carers and the clinical team. 4. Assess the relative risks on an individual patient basis, and if this supports use of a paclitaxel DCB or DES, ensure that: a) the documentation of informed consent includes a risk-benefit discussion with the patient and their family or carers regarding the uncertainty in long-term outcomes with these devices, and the current evidence which indicates an increased risk of mortality. b) b) the patient receives clinically appropriate follow-up. This may include face to face or telephone consultations in the hospital or the community.

	5. Ensure local procedures accounting for duty of candour are in place for the continued management of patients who have already been treated with paclitaxel DCBs an DESs. Consider the provision of information and advice to address any patient concerns arising from the current uncertainty in long-term outcomes associated with these devices. For more information, Click Here. If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through: NCMDR Vigilance system 19999 unified call center