



HEALTH SCIENCES AUTHORITY
7 JUNE 2019

PACLITAXEL-COATED BALLOONS (PCB) AND PACLITAXEL-ELUTING STENTS (PES) USED TO TREAT PERIPHERAL ARTERIAL DISEASE (PAD) – POTENTIAL INCREASE OF MORTALITY RISK

Paclitaxel-coated balloons (PCB) and Paclitaxel-eluting stents (PES) are used to treat de novo or restenotic lesions in the leg to open obstructed vessels. Peripheral arterial diseases (PAD) typically develops when arteries are narrowed and restrict blood flow due to build-up of plaque. There are PCB and PES devices registered in Singapore and also in overseas jurisdictions for treating PAD. The Paclitaxel released from these devices is intended to reduce restenosis in the artery.

A systematic review and meta-analysis of randomised controlled trials published in the Journal of the American Heart Association* has identified a possible relationship between increased risk of death at 2 to 5 years after the use of PCB and PES devices to treat PAD. The reason for this possible increased risk is still unclear and is being assessed globally by the regulators.

- As a precautionary measure, until additional information is available, healthcare professionals as part of their standard care are reminded to:
 - Continue surveillance of patients who have been treated with paclitaxel-containing devices for PAD in accordance with current standard of care
 - Weigh the clinical benefit and risks for each patient when considering the use of PCB and PES devices

Healthcare professionals are reminded to report all medical device related adverse events to the Medical Devices Branch, Medical Devices Cluster, Health Products Regulation Group, HSA at Tel: 6866 1048, Email: HSA_Medical_Device@hsa.gov.sg, or report online at www.hsa.gov.sg/ae_online.

*Katsanos, K., Spiliopoulos, et al. Risk of Death Following Application of Paclitaxel-Coated Balloons and Stents in the Femoropopliteal Artery of the Leg: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. *Journal of the American Heart Association*, 2018;7(24).

Please feel free to contact the following officers for any clarifications regarding this communication.

Dr Zhong Yanxin - Tel: 6866 3505 (DID); email: ZHONG_Yanxin@hsa.gov.sg

Dr Christopher Lam - Tel: 6304 5455 (DID); email: Christopher_LAM@hsa.gov.sg

**MEDICAL DEVICES BRANCH
MEDICAL DEVICES CLUSTER
HEALTH PRODUCTS REGULATION GROUP
HEALTH SCIENCES AUTHORITY
SINGAPORE
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About the Health Sciences Authority (HSA)

The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services and Applied Sciences, to protect and advance national health and safety. HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. As the national blood service, it is responsible for providing a safe and adequate blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit <http://www.hsa.gov.sg/>.

For more updates on public health and safety matters, follow us on Twitter at www.twitter.com/HSAsg.

About HSA's Health Products Regulation Group

The Health Products Regulation Group (HPRG) of HSA ensures that drugs, innovative therapeutics, medical devices and health-related products are wisely regulated and meet appropriate safety, quality and efficacy standards. It contributes to the development of biomedical sciences in Singapore by administering a robust, scientific and responsive regulatory framework.