Australian Government

Department of Health
Therapeutic Goods Administration

Therapeutic Goods Act 1989

Notification under section 42DF of approval of use of restricted representations by Medical Developments International Ltd

I, Leanne McCauley, Delegate of the Secretary to the Department of Health for the purposes of section 42DF of the *Therapeutic Goods Act 1989* (the Act), advise that following receipt of an application from Medical Developments International Ltd, the restricted representations described in paragraph (a) (i) – (v) below for use in advertisements directed to consumers, for the product identified in paragraph (b) were approved on 6 December 2019:

(a)

(i) Designed to deliver medication into the lungs for patients with asthma and COPD;

(ii) For delivering asthma and COPD medication with most puffers or pressurised metered dose inhalers (pMDIs);

(iii) Can be used with standard 22 mm outer diameter mouth piece fitting for the delivery of asthma and COPD medication;

(iv) Designed to improve the delivery of asthma and COPD medication to the small airways deep within the lungs;

(v) *A compact spacer for use with most standard puffers in the treatment of asthma and COPD.*

(b) Medicine chamber spacers entered in the Australian Register of the Therapeutic Goods (ARTG) under identification number 142303.

Dated this 6th day of December 2019

Signed electronically

Leanne McCauley
Delegate of the Secretary to the Department of Health
Advertising Compliance Unit
Regulatory Education and Compliance Branch