Australian Government
Department of Health

Ministerial Submission – Standard
MS19-000434 Version (1)
Date sent to MO: 01/03/19

To: Minister Hunt

Subject: MEDICAL DEVICE CONSULTATIONS – THIRD PACKAGE

Critical date: 18 March 2019 to enable public consultations to be conducted until 29 April 2019.

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The consultation paper at Attachment E **proposes to introduce a new classification rule for substances introduced into the body via body orifice or applied to the skin.** This includes examples such as weight loss capsules that expand in the stomach; vaginal gels that maintain pH balance or treat bacterial vaginosis; salivation stimulation lozenges, throat lozenges and saline nasal solution sprays. It is proposed that these devices will be reclassified from low-risk/low-medium risk (Class I/Class IIa) to low-medium/medium/high risk (Class IIa/Class IIb/Class III) depending on the location in the body and where the device achieves its intended purpose.

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