Provisional Consent to the Distribution of New Medicines

Pursuant to section 23(1) of the Medicines Act 1981, the Minister of Health hereby provisionally consents to the sale, supply or use in New Zealand of the new medicines set out in the Schedule hereto:

Schedule

Product:	**Estradiol**
Active Ingredient:	Estradiol hemihydrate 0.41mg
Dosage Form:	Transdermal patch
New Zealand Sponsor:	Viatris Limited
Manufacturer:	Mylan Technologies, Vermont, United States of America

Note: This consent is given subject to the following conditions:

1. The medicine may only be marketed or distributed when no other estradiol transdermal patch medicine with consent under section 20 of the Medicines Act 1981 is available in the New Zealand market, or to meet PHARMAC supply obligations.
2. The sponsor must produce and distribute a Dear Healthcare Professional letter detailing the differences between the package inserts and the indications and dosing and administration instructions approved for the product in New Zealand, within two weeks following consent.

Note: This consent is valid for two years from the date of publication of this notice.

Product:	**Estradiol**
Active Ingredient:	Estradiol hemihydrate 0.82mg
Dosage Form:	Transdermal patch
New Zealand Sponsor:	Viatris Limited
Manufacturer:	Mylan Technologies, Vermont, United States of America

Note: This consent is given subject to the following conditions:

1. The medicine may only be marketed or distributed when no other estradiol transdermal patch medicine with consent under section 20 of the Medicines Act 1981 is available in the New Zealand market, or to meet PHARMAC supply obligations.
2. The sponsor must produce and distribute a Dear Healthcare Professional letter detailing the differences between the package inserts and the indications and dosing and administration instructions approved for the product in New Zealand, within two weeks following consent.

Note: This consent is valid for two years from the date of publication of this notice.

Product:	**Estradiol**
Active Ingredient:	Estradiol hemihydrate 1.23mg
Dosage Form:	Transdermal patch
New Zealand Sponsor:	Viatris Limited
Manufacturer:	Mylan Technologies, Vermont, United States of America

Note: This consent is given subject to the following conditions:

1. The medicine may only be marketed or distributed when no other estradiol transdermal patch medicine with consent under section 20 of the Medicines Act 1981 is available in the New Zealand market, or to meet PHARMAC supply obligations.
2. The sponsor must produce and distribute a Dear Healthcare Professional letter detailing the differences between the package inserts and the indications and dosing and administration instructions approved for the product in New Zealand, within two weeks following consent.

Note: This consent is valid for two years from the date of publication of this notice.

Product:	**Estradiol**
Active Ingredient:	Estradiol hemihydrate 1.64mg
Dosage Form:	Transdermal patch

New Zealand Sponsor:	Viatris Limited
Manufacturer:	Mylan Technologies, Vermont, United States of America

Note: This consent is given subject to the following conditions:

1. The medicine may only be marketed or distributed when no other estradiol transdermal patch medicine with consent under section 20 of the Medicines Act 1981 is available in the New Zealand market, or to meet PHARMAC supply obligations.
2. The sponsor must produce and distribute a Dear Healthcare Professional letter detailing the differences between the package inserts and the indications and dosing and administration instructions approved for the product in New Zealand, within two weeks following consent.

Note: This consent is valid for two years from the date of publication of this notice.

Dated this 13th day of June 2023.

CHRIS JAMES, Group Manager, Medsafe, Ministry of Health (pursuant to delegation given by the Minister of Health on 11 September 2013).

2023-go2497 15-06-2023 09:03