

**CAPECITABIINE**

**tablets, 150 mg and 500 mg;**

**Xeloda<sup>®</sup>, Roche Products Pty Ltd;**

**Capecitabine Actavis<sup>®</sup>, Actavis Pty Ltd;**

**Capecitabine Alphapharm<sup>®</sup>, Alphapharm Pty Ltd;**

**Capecitabine Apotex<sup>®</sup>, Apotex Pty Ltd;**

**Capecitabine-DRLA<sup>®</sup>, Dr Reddy's Laboratories (Australia) Pty Ltd;**

**Capecitabine GH<sup>®</sup>, Generic Health Pty Ltd;**

**Capecitabine Sandoz<sup>®</sup>, Sandoz Pty Ltd;**

**Xelabine<sup>®</sup>, Aspen Pharma Pty Ltd.**

**MEGESTROL**

**tablet, 160 mg;**

**Megace<sup>®</sup>, Aspen Pharma Pty Ltd.**

**TOREMIFENE**

**tablet, 60 mg;**

**Fareston<sup>®</sup>, Merck Sharp & Dohme (Australia) Pty Ltd.**

**VINORELBINE**

**vials for injection, 10 mg/mL injection, 1 x 1 mL vial and 50 mg/5 mL injection, 1 x 5 mL vial, Hospira Pty Ltd;**

**Navelbine<sup>®</sup>, Pierre Fabre Medicament Australia Pty Ltd;**

**Vinorelbine Ebewe<sup>®</sup>, Sandoz Pty Ltd;**

**Vinorelbine Kabi<sup>®</sup>, Fresenius Kabi Australia Pty Ltd.**

Correspondence from the Medical Oncology Group of Australia (MOGA) seeking to make the PBS restrictions less restrictive dated 18 September 2014. (12.4)

**1 Purpose of Item**

- 1.1 The Medical Oncology Group of Australia (MOGA) sought to have the drugs capecitabine, megestrol, toremifene and vinorelbine (injection presentation only) made available as unrestricted pharmaceutical benefits based on the view that the long history of PBS listing has made these drugs significantly less costly compared to alternative PBS listed treatments for later lines of therapy and on the view that they are unlikely to be prescribed for conditions outside of those for which they are currently PBS-listed irrespective of the PBS restriction level placed on them.

## **2 Background**

2.1 At the time of MOGA's request, the four drugs referred to by MOGA had the following PBS restrictions in November 2014:

### **CAPECITABINE:**

Authority Required

Advanced breast cancer after failure of prior therapy which includes a taxane and an anthracycline

Authority Required

Advanced breast cancer where therapy with a taxane and/or an anthracycline is contraindicated

Authority Required

Advanced breast cancer in combination with docetaxel after failure of prior anthracycline-containing chemotherapy

Authority Required

Treatment of advanced or metastatic colorectal cancer

Authority Required

Adjuvant treatment of stage III (Dukes C) colon cancer, following complete resection of the primary tumour either as:

(a) monotherapy; or

(b) in combination with oxaliplatin

Authority Required

Advanced (Stage III or IV) oesophago-gastric cancer, previously untreated, in combination with a cisplatin-based regimen, in a patient with a WHO performance status of 2 or less

NOTE:

In the adjuvant setting, the recommended treatment duration is 24 weeks.

Capecitabine is not PBS-subsidised for the treatment of patients with stage II (Dukes B) colon cancer.

Capecitabine is not PBS-subsidised for the adjuvant treatment of patients with rectal cancer.

### **MEGESTROL:**

Restricted Benefit

Hormone-dependent advanced breast cancer

### **TOREMIFENE:**

Restricted Benefit

Treatment of hormone-dependent metastatic breast cancer in post-menopausal patients

NOTE:

This drug is not PBS-subsidised for primary prevention of breast cancer.

**VINORELBINE (injection form):**

Authority Required (STREAMLINED)

3890

Locally advanced or metastatic non-small cell lung cancer

Authority Required (STREAMLINED)

3907

Advanced breast cancer after failure of prior therapy which includes an anthracycline

- 2.2 The PBAC recalled that it had considered a request of the same nature with respect to docetaxel and paclitaxel at its July 2014 meeting.

**3 PBAC Outcome**

- 3.1 The PBAC agreed with the MOGA view that the patterns of use of these drugs is unlikely to be influenced by the PBS restriction level given the long history of PBS-listing and emergence of more targeted therapies in recent times. The PBAC noted that the MOGA request had been made with reference to the breast cancer indications of the four drugs but that capecitabine's listing also includes a metastatic colorectal cancer indication and vinorelbine's listing also includes a non-small cell lung cancer indication. However, the PBAC had no objections to these four drugs becoming unrestricted benefits on the PBS.

**Outcome:**

Recommended

**4 Recommended listing**

- 4.1 Amend existing Restriction level to 'unrestricted' for the following PBS item codes:

Capecitabine: 8361C (150 mg tablet), 8362D (500 mg tablet)

Megestrol: 2734X

Vinorelbine: 4620E (Chemotherapy item for Public Hospital use), 7263G (Chemotherapy item for Private Hospital/Private Clinic use)

Toremifene: 8216K

- 4.2 There are no other changes to the listings.

**5 Context for Decision**

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to

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recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.