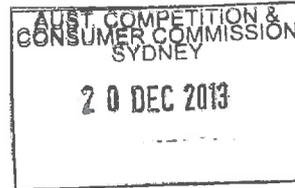


Our reference
MM/JM/JANS1951-9093597

8 Chifley
8-12 Chifley Square Sydney NSW 2000
GPO Box 9925 NSW 2001
Tel (02) 9210 6500
Fax (02) 9210 6611
www.corrs.com.au



Sydney
Melbourne
Brisbane
Perth



20 December 2013

By hand delivery

Dr Richard Chadwick
General Manager - Adjudication Branch
Australian Competition and Consumer
Commission
Level 20, 175 Pitt Street

Contact
Jackie Mortensen (02) 9210 6530
Email: jackie.mortensen@corrs.com.au

Partner
Mark McCowan (03) 9672 3335
Email: mark.mccowan@corrs.com.au

SYDNEY NSW 2000

Dear Dr Chadwick

Janssen-Cilag Pty Ltd: Notification of exclusive dealing

We act for Janssen-Cilag Pty Ltd.

Enclosed is an exclusive dealing notification pursuant to section 93(1) of the *Competition and Consumer Act 2010* (Cth) lodged on behalf of our client, together with a cheque in the amount of \$100.00 in payment of the lodgement fee.

Yours sincerely

A handwritten signature in blue ink, appearing to be 'Mark McCowan'.

Mark McCowan
Partner

attachments

Form G

Commonwealth of Australia
Competition and Consumer Act 2010 subsection 93 (1)

NOTIFICATION OF EXCLUSIVE DEALING

To the Australian Competition and Consumer Commission:

Notice is hereby given, in accordance with subsection 93 (1) of the *Competition and Consumer Act 2010*, of particulars of conduct or of proposed conduct of a kind referred to subsections 47 (2), (3), (4), (5), (6), (7), (8) or (9) of that Act in which the person giving notice engages or proposes to engage.

PLEASE FOLLOW DIRECTIONS ON BACK OF THIS FORM

1. Applicant

- (a) Name of person giving notice:

(Refer to direction 2)

Janssen-Cilag Pty Ltd (ACN 000 129 975) (JCA)

- (b) Short description of business carried on by that person:

(Refer to direction 3)

JCA is a research-based pharmaceutical company. JCA provides prescription medicines for a range of conditions in the areas of mental health, neurology, women's health, haematology, oncology, gastroenterology, and pain management.

- (c) Address in Australia for service of documents on that person:

C/- Mark McCowan
Corrs Chambers Westgarth
8 Chifley
8-12 Chifley Square
SYDNEY NSW 2000

2. Notified arrangement

- (a) Description of the goods or services in relation to the supply or acquisition of which this notice relates:

A subsidised access program for Zytiga®, a therapeutic drug referred to in more detail in paragraph (b) below, managed by Vivacity Health Pty Ltd on behalf of JCA, (**Program**), under which Zytiga® will be supplied to patients accepted to the Program by a central dispensing pharmacy, East Gosford Pharmacy, which has been accredited by the Pharmaceutical Benefits Scheme (PBS) and Pharmacy Guild of Australia's Quality Care Pharmacy Program (QCPP).

(b) Description of the conduct or proposed conduct:

(Refer to direction 4)

Zytiga® is used in the treatment of metastatic advanced prostate cancer. Zytiga® is only available on prescription and is taken with the therapeutic drug prednisone or prednisolone. Currently, Zytiga® is only subsidised through the PBS for men with disease progression after they have received chemotherapy (**Indication I**).

Zytiga was recently approved by the Therapeutic Goods Administration (TGA) for use with metastatic prostate cancer for men who have failed hormonal therapy (**Indication II**). Zytiga® is not currently available through the PBS for Indication II.

JCA is proposing to establish the Program to assist patients to cover the cost of treatment with Zytiga® for Indication II, which is not currently subsidised through the PBS.

The Program will be co-ordinated and administered by Vivacity Health, a medical education agency. Vivacity Health will be the liaison between JCA, patients, medical practitioners and the central dispensing pharmacy, East Gosford Pharmacy.

The Program will operate until Zytiga® is listed on the PBS for Indication II (subject to JCA continuing to have the ability to supply Zytiga®).

JCA intends the Program to operate as follows:

- for a patient enrolled into the Program, JCA will cover the cost of Zytiga® every alternate month between the first and the sixteenth month of treatment; and
- JCA will cover the ongoing cost of Zytiga® from the seventeenth month of treatment and beyond.

Eligibility to the Program will be aligned with the TGA approval for Indication II and an expected future PBS authority listing. Namely, a patient who has castration resistant metastatic carcinoma of the prostate who has failed androgen deprivation therapy and who is asymptomatic or mildly symptomatic of their prostate cancer will be eligible for the Program. All patients who meet the eligibility requirements will be accepted to the Program.

JCA is proposing to enter into an arrangement with East Gosford Pharmacy, a central PBS and QCPP accredited dispensing pharmacy, to supply Zytiga® to those patients who are accepted to the Program. Patients who are accepted to the Program will only be able to obtain subsidised access to Zytiga® from the central pharmacy. Patients will be able to purchase prednisone or prednisolone from any pharmacy if they so wish.

3. Persons, or classes of persons, affected or likely to be affected by the notified conduct

(a) Class or classes of persons to which the conduct relates:

(Refer to direction 5)

Patients who are accepted to the Program

East Gosford Pharmacy

Vivacity Health

JCA

(b) Number of those persons:

(i) At present time:

None

(ii) Estimated within the next year:

(Refer to direction 6)

In excess of 50 patients.

(c) Where number of persons stated in item 3 (b) (i) is less than 50, their names and addresses:

N/A

4. Public benefit claims

- (a) Arguments in support of notification:
(Refer to direction 7)

At present, Zytiga® is not listed on the PBS for Indication II.

In the absence of this program, each patient that is prescribed Zytiga® for Indication II would be required to pay approximately \$3,700 for each month of treatment (although the exact figure will depend on the final price set by the pharmacy, which differ from pharmacy to pharmacy, and may be substantially more). Approximately half of the men treated with Zytiga® for Indication II can expect to require more than 16 months of treatment.

Patients who are enrolled in the Program (as referred to above) will receive subsidised access to Zytiga® and will be expected to pay up to \$3,700 each alternate month between the first and sixteen month of treatment. That is, a patient's maximum payment for their Zytiga® will be capped at eight bottles. JCA will meet the cost of the patient's Zytiga® on the other months, and from month 17 and beyond. This will allow patients, who otherwise may not have been able to afford Zytiga® for Indication II, access to medication that will assist in the treatment of their prostate cancer.

The \$3,700 monthly amount payable by the patient under the Program includes a one month supply of Zytiga® and prednisone or prednisolone (if the patient elects to purchase prednisone or prednisolone from East Gosford Pharmacy), a dispensing fee, and a shipping fee for home delivery, a merchant fee, and any other fee that may be imposed by East Gosford Pharmacy.

For those months where JCA meets the cost of the patient's Zytiga®, the patient must meet the cost of their prednisone or prednisolone (if the patient elects to purchase prednisone or prednisolone from East Gosford Pharmacy), and any dispensing fees, a shipping fee for home delivery, a merchant fee, and any other fee that may be imposed by East Gosford Pharmacy. This cost will be approximately \$45 per month.

JCA is proposing to enter into the arrangement with Vivacity Health and East Gosford Pharmacy to supply Zytiga® under the Program for the following reasons:

- efficiency, ease of traceability of stock and audit. During the first sixteen months of the Program, a patient will be provided with a single script for two months' supply of Zytiga®. The two months' supply of Zytiga® is provided to East Gosford Pharmacy, but only a month's supply of Zytiga® is dispensed to a patient at one time. Should a patient withdraw from the Program without obtaining the second month supply of Zytiga® the pharmacy will be left with excess stock. Should this stock not be returned to JCA, this is an expense incurred by JCA which will have cost implications for the Program. Using a central pharmacy allows for greater efficiency, ease of traceability and audit of excess stock, for both JCA and Vivacity Health, which in turn reduces the administration costs of the Program, allowing this money to be used, for example, in supplying other patients with Zytiga® under the Program or for other programs;

- JCA is intending to impose a ceiling price, above which East Gosford Pharmacy cannot sell Zytiga® to patients, for every second month of the first sixteen months of the Program, to ensure that East Gosford Pharmacy does not seek to sell Zytiga® to patients at an excessively high price. This would not be commercially possible if an alternate wholesale supply model was adopted;
- Vivacity Health and East Gosford Pharmacy have experience in running access programs, which will further serve to reduce administration costs of the Program; and
- East Gosford Pharmacy will ship the medicine direct to patients' homes. This is important in circumstances where Zytiga® is not commonly stocked by pharmacies as a general inventory item, because of its price, and so patients will not be required to visit a pharmacy twice to obtain Zytiga® (the first time to provide the prescription to the pharmacy and the second time to collect the Zytiga®).

(b) Facts and evidence relied upon in support of these claims:

See above.

5. Market definition

Provide a description of the market(s) in which the goods or services described at 2 (a) are supplied or acquired and other affected markets including: significant suppliers and acquirers; substitutes available for the relevant goods or services; any restriction on the supply or acquisition of the relevant goods or services (for example geographic or legal restrictions):

(Refer to direction 8)

JCA has not formed a concluded view as to the relevant market(s) for the purpose of analysing the proposed conduct.

The conduct will affect:

- the supply of medicine used to treat metastatic prostate cancer, including the supply of Zytiga®, in Australia;
- the supply of retail pharmaceutical services; and
- the supply of health program management services.

6. Public detriments

(a) Detriments to the public resulting or likely to result from the notification, in particular the likely effect of the notified conduct on the prices of the goods or services described at 2 (a) above and the prices of goods or services in other affected markets:

(Refer to direction 9)

There is no public detriment resulting or likely to result from the notification for the following reasons:

- Zytiga® will continue to be supplied to pharmacies and can be

purchased from any pharmacy by patients not accepted to the Program;

- there are alternative treatments for metastatic prostate cancer (for example, Taxotere®, Jevtana®) which can be purchased from any pharmacy; and
- after the first sixteen months of the Program, prednisone or prednisolone can be purchased from any pharmacy for use with Zytiga® provided under the Program.

(b) Facts and evidence relevant to these detriments:

See above.

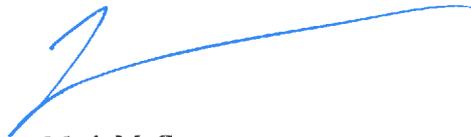
7. Further information

- (a) Name, postal address and contact telephone details of the person authorised to provide additional information in relation to this notification:

Mark McCowan
Corrs Chambers Westgarth
8 Chifley
8-12 Chifley Square
SYDNEY NSW 2000

Dated 20/12/13

Signed by/on behalf of the applicant Janssen-Cilag Pty Ltd (ACN 000 129 975)



Mark McCowan

Partner

Corrs Chambers Westgarth



DIRECTIONS

- 1 In lodging this form, applicants must include all information, including supporting evidence that they wish the Commission to take into account in assessing their notification.

Where there is insufficient space on this form to furnish the required information, the information is to be shown on separate sheets, numbered consecutively and signed by or on behalf of the applicant.

- 2 If the notice is given by or on behalf of a corporation, the name of the corporation is to be inserted in item 1 (a), not the name of the person signing the notice, and the notice is to be signed by a person authorised by the corporation to do so.
- 3 Describe that part of the business of the person giving the notice in the course of the which the conduct is engaged in.
- 4 If particulars of a condition or of a reason of the type referred to in section 47 of the *Competition and Consumer Act 2010* have been reduced in whole or in part to writing, a copy of the writing is to be provided with the notice.
- 5 Describe the business or consumers likely to be affected by the conduct.
- 6 State an estimate of the highest number of persons with whom the entity giving the notice is likely to deal in the course of engaging in the conduct at any time during the next year.
- 7 Provide details of those public benefits claimed to result or to be likely to result from the proposed conduct including quantification of those benefits where possible.
- 8 Provide details of the market(s) likely to be affected by the notified conduct, in particular having regard to goods or services that may be substitutes for the good or service that is the subject matter of the notification.
- 9 Provide details of the detriments to the public which may result from the proposed conduct including quantification of those detriments where possible.