

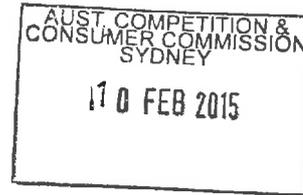
Our reference
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10 February 2015

By hand

Adjudication Branch
Australian Competition and Consumer Commission
Level 20, 175 Pitt Street
Sydney NSW 2000

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

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

Dear Sir/Madam

Janssen-Cilag Pty Ltd - Notification of exclusive dealing

We act for Janssen-Cilag Pty Ltd (**Janssen**).

Janssen is seeking immunity in relation to potential third line forcing conduct arising from the establishment of a program for the dispensing of, supply to, and administration and payment of certain medications to (and by) mental health patients as part of a broader support program for mental health patients, on the condition that the medications are obtained from certain participating pharmacies.

We **enclose** a completed Form G Notification of Exclusive Dealing and an EFT receipt for the lodgement fee.

Should you require any further information regarding any aspect of the notified conduct, please do not hesitate to contact me on (02) 9210 6533 or Jackie Mortensen on (02) 9210 6530.

Yours sincerely

Mark McCowan
Partner

attachments

10 FEB 2015

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)*N98121 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
Level 9, 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:

JCA propose to establish a program for the easy dispensing of, supply to, and administration and payment of (together, the **Services**) the pharmaceutical products, INVEGA SUSTENNA® and/or RISPERDAL CONSTA® (**Medications**), to (and by) mental health patients (**Program**) as part of a broader support program for mental health patients.

The Program will be managed by Partizan Worldwide Pty Ltd (ACN 115 985 825) (**Partizan**).

- (b) Description of the conduct or proposed conduct:

(Refer to direction 4)

INVEGA SUSTENNA® (paliperidone palmitate) is an atypical antipsychotic medicine used to treat the symptoms of schizophrenia. It helps to correct a

chemical imbalance in the brain associated with this condition. INVEGA SUSTENNA® is manufactured as a modified release aqueous suspension for intramuscular injection by a healthcare professional. Once a patient receives the first dose of INVEGA SUSTENNA®, the second dose needs to be administered one week later and subsequent doses are once per month.

RISPERDAL CONSTA® (risperidone) is an atypical antipsychotic medicine used to treat the symptoms of schizophrenia, bipolar disorder and other types of related psychoses. It helps to correct a chemical imbalance in the brain associated with these conditions. RISPERDAL CONSTA® is manufactured in powder form, which is reconstituted with the diluent supplied in the package. Following reconstitution, RISPERDAL CONSTA® is administered by intramuscular injection by a healthcare professional. A patient receives a dose every two weeks.

Under the Program, the Services will be provided to mental health patients who are currently being treated either in the Community Mental Health (CMH) system or by general practitioners (GPs), are prescribed the Medications and who have nominated to participate in the Program (**Participating Patients**).

Many mental health patients, in particular those who are transitioning from a scenario of case management in a CMH facility to care by a GP, have difficulty managing the process of script renewal, medication collection and storage, appointment making and medication administration within strict intervals. As a result, mental health patients may not comply with the regime required by schizophrenia medication treatment.

In addition, many mental health patients find it difficult to afford and manage the co-payment for the Medications. This is the amount payable by the patient for the Medications under the Pharmaceutical Benefits Scheme. While many mental health patients are also concession card holders (and are responsible only for the concessional co-payment (which is currently \$6.10)), patients often have difficulties making this payment. Ultimately, a pharmacy may not dispense the Medications to a patient where the patient is unable to pay the co-payment. This can also lead to non-compliance with the regimented regime for the Medications.

JCA has therefore developed the Program to simplify the medication process for patients with schizophrenia. Under the Program, a Participating Patient will not be required to attend their GP to obtain a prescription for the Medications, provide that prescription directly to a pharmacy to have the Medications dispensed, obtain the Medications from a pharmacy, attend the pharmacy to make payment for the Medications, or store the Medications prior to attending an appointment with their GP for the Medications to be administered.

Under the Program:

- a Participating Patient's CMH treating healthcare professional (in the case of remaining repeat prescription at the commencement of the Program) or GP will provide the Participating Patient's prescription for the Medications to a CMH nominated retail pharmacy;
- the Medications will be dispensed by the CMH nominated retail pharmacy and delivered directly to the Participating Patient's GP;
- the Participating Patient will attend their GP to have the Medications administered by the GP;
- the Participating Patient's concessional co-payment for the Medication

will be paid directly to the CMH nominated retail pharmacy on the Participating Patient's behalf by a means chosen by the Participating Patient (this may include a direct debit arrangement or an arrangement made through financial support programs, including government programs, which the Participating Patient may be entitled to access (such as, Closing the Gap, Centrepay and the State Trustee)); and

- Partizan will monitor whether a Participating Patient is receiving the Medications and will follow-up with the CMH nominated retail pharmacy, the Participating Patient's GP and/or the Participating Patient as applicable.

The Program is to be co-ordinated and administered by Partizan, a business that specialises in patient engagement. It is proposed that Partizan will be the liaison between JCA, CMH nominated retail pharmacies, GPs and Participating Patients.

Under the Program, JCA, via its service provider Partizan, proposes to offer to supply and to supply the Services to a Participating Patient on the condition that the Participating Patient acquires the Medications from a CMH nominated retail pharmacy.

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)

The affected classes of persons are as follows:

- Participating Patients;
- Participating Patients' GPs;
- CMH nominated retail pharmacies;
- Partizan; and
- JCA.

- (b) Number of those persons:

- (i) At present time:

None at present.

- (ii) Estimated within the next year:
(Refer to direction 6)

More than 50 persons.

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

Not applicable.

4. Public benefit claims

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

As noted above, a mental health patient who is prescribed the Medications has to:

- attend their GP to obtain a prescription for the Medications;
- provide that prescription to a pharmacy to have the Medications dispensed;
- obtain the Medications from a pharmacy;
- attend the pharmacy to make payment for the Medications;
- store the Medications; and
- attend an appointment with their GP for the Medications to be administered.

This responsibility can be burdensome for many mental health patients, particularly for those with schizophrenia who have recently transitioned from the CMH system to care by a GP, and may result in patients failing to comply with the regimented regime for the Medications.

The Program will, therefore, result in the following benefits to the public:

- better health outcomes for Participating Patients, which will lead to a reduction in the need for rehospitalisation of the Participating Patients and, ultimately, in the overall burden on the broader health system as a result of:
 - an increased number of mental health patients receiving the Medications in accordance with the required regime. The Program is expected to increase the number of individuals receiving appropriate treatment, including by decreasing the number of “no-shows” of patients at GP appointments for the administration of the Medications;
 - mental health patients who are transitioning from the CMH system to care by a GP receiving a significant level of support and care, making their adjustment to community life easier and ensuring continuity of care in circumstances where they may otherwise not be monitored as closely; and
 - a removal of the burden on mental health patients of arranging payment to a third party, including ensuring that they have sufficient funds; and
- CMH nominated retail pharmacies will have greater certainty that the co-payment will be paid when they dispense the Medication, and there will be a corresponding reduction in the number of patients who are unable to pay. CMH nominated retail pharmacies will therefore be motivated to provide high levels of service in order to remain in the Program.

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

See paragraph 4(a) 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 proposed conduct will affect:

- the supply of prescription-only anti-psychotic medicines used to treat schizophrenia, including the Medications, 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)

To the extent that any public detriment arises from the notified conduct, which in JCA's view is unlikely, any such detriment would be minimal and would be outweighed by the benefits outlined at paragraph 4(a) above.

JCA acknowledges that some non-CMH nominated retail pharmacies may lose the ability to supply the Medications to Participating Patients – although there is a question as to whether any loss would in fact arise in circumstances where many patients may not fulfil their scripts for the Medications and/or may not have the ability to pay the co-payment amount without the Program.

To the extent that there is any public detriment, JCA considers that it will be minimal for the following reasons:

- participation is entirely voluntary for patients, pharmacies, GPs and Partizan. Participating Patients are free to continue using their own GPs and will be able to opt-out at any time;
- the Medications will continue to be supplied to pharmacies, including non-CMH nominated retail pharmacies, and will be able to be purchased from any pharmacy by non-Participating Patients;
- Participating Patients may elect to participate only in certain elements of the Program, such that they can purchase their Medications from any non-CMH nominated retail pharmacies; and

- there are numerous alternative treatments for schizophrenia which can be purchased from any pharmacy.

(b) Facts and evidence relevant to these detriments:

See paragraph 6(a) 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
Level 9, 8 Chifley
8-12 Chifley Square
SYDNEY NSW 2000

Dated

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 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.