

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)

N98054 Novartis Pharmaceuticals Australia Pty Limited (ABN 18 004 244 160)
(**Novartis**)

- (b) Short description of business carried on by that person:
(Refer to direction 3)

Novartis is a member of the Novartis group of companies and specialises in production of innovative prescription pharmaceutical products to prevent and cure diseases, ease suffering and to enhance the quality of life.

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

Group General Counsel

Novartis Group (Australia and New Zealand)

54 Waterloo Road

North Ryde, NSW 2113

2. Notified arrangement

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

This notification relates to the proposed offer by Novartis to the Australian Pharmacy Group (**APG**) of supply of the Novartis product, Jakavi, which is a medicine used to treat adult patients with myelofibrosis, a rare form of blood disorder. Jakavi contains the active substance ruxolitinib phosphate and belongs to a group of medicines called Jak inhibitors.

Myelofibrosis is a disorder of the bone marrow, in which the marrow is replaced by scar tissue. The abnormal marrow can no longer produce enough normal blood cells and results in a significantly enlarged spleen.

Jakavi can reduce spleen size in patients with different forms of myelofibrosis and relieve the symptoms.

Jakavi is authorised by the Therapeutic Goods Administration to be supplied in Australia where prescribed by a treating physician but is not currently listed on the Pharmaceutical Benefits Scheme.

Jakavi is available for supply to various wholesalers and other customers in Australia, and is available for dispensing through both hospital and retail pharmacies.

Novartis proposes to support a specific patient co-payment programme, which is termed "**Jakavi PayShare**" in conjunction with APG, which is intended to provide access to patients who cannot currently access it without paying full retail price. Jakavi is the first JAK1 and JAK2 inhibitor approved by the Therapeutic Goods Administration (TGA) for the treatment of myelofibrosis (MF), a rare bone marrow disorder where the marrow is replaced by scar tissue, and exhibits a variety of symptoms such as fever, night sweats, bone pain, weight loss, and significantly enlarged spleen. Jakavi can improve disease related symptoms and reduce spleen volume in newly diagnosed patients, or those intolerant of, resistant or refractory to best available therapy.

Under the Jakavi PayShare program, Novartis proposes to offer supply of Jakavi to APG at a discount in order for APG to supply Jakavi to patients participating in the PayShare program at a corresponding discount.

Participation in Jakavi Payshare will be voluntary and patients will have the choice of continuing to acquire Jakavi from other pharmacists outside the Jakavi PayShare program.

As part of the Jakavi PayShare program, Novartis has contracted Nexus Australasia Pty Limited (trading as Zest Healthcare Communications) (**Zest**) to develop an electronic payment portal for patients to use to pay for their supplies of Jakavi. The portal will be hosted and administered by Zest, who will track orders, payments and information provided by patients via the portal and pass this information on to APG in order for it to dispense the products to patients.

- (b) Description of the conduct or proposed conduct:
(Refer to direction 4)

Novartis proposes to:

- (i) supply, or offer to supply, Jakavi to APG at discounted prices for APG to supply to patients in response to orders placed by patients using of the PayShare Portal; and
- (ii) refuse to supply Jakavi to APG at the discounts proposed in the context of the PayShare programme other than where those products have been ordered via the PayShare Portal.

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)

APG and patients

- (b) Number of those persons:

- (i) At present time:

None – the PayShare Portal has not yet launched

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

In excess of 300 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)

Novartis considers that the proposed conduct will provide the following benefits:

- [provide access to patients who cannot currently access it without paying full retail price;]
- Ability of APG to readily coordinate patient orders and the delivery process and receive payments through the online portal which has already been developed by Zest for Novartis;
- Ensuring the PayShare programme is run efficiently and in a streamlined way as the PayShare Portal developed by Zest allows prescription and patient information to be populated, coordination of orders and delivery process and patients to make payment for the products.

- (b) Facts and evidence relied upon in support of these claims:
See item (4) 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)

The wholesale market for the supply of pharmaceutical products in Australia.

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)

The proposed conduct is not likely to result in any public detriments.

Patients may elect to join the Jakavi PayShare program or acquire Jakavi separately.

Other pharmacists outside the Jakavi PayShare program will continue to be able to source and supply Jakavi.

APG is currently limited to using Zest to provide the online portal and coordinate orders and the delivery process for Jakavi products to consumers participating in PayShare, as Zest is the only entity that can currently provide the infrastructure required to run the PayShare programme. Patients who are not participating in the Jakavi PayShare program are not required to use the PayShare Portal, and APG is not restricted from using other electronic payment portals outside the PayShare programme.

- (b) Facts and evidence relevant to these detriments:
See item 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:

Group General Counsel

Novartis Group (Australia and New Zealand)

7. Further information

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

Group General Counsel

Novartis Group (Australia and New Zealand)

54 Waterloo Road

North Ryde NSW 2113

Dated..... 8/12/2014

Signed by/on behalf of the applicant

.....
(Signature)

Ray Steinwall
.....
(Full Name)

Novartis Pharmaceuticals Australia P/L
.....
(Organisation)

General Counsel
.....
(Position in Organisation)

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.