



RESPONSE TO ACCC'S REQUEST FOR FURTHER INFORMATION DATED 6 JUNE 2022

Red is confidential to Celgene and Natco/Juno (not to be shared with the public)

Green is confidential to Celgene (not to be shared with Natco/Juno or the public)

Blue is confidential to Natco/Juno (not to be shared with Celgene or the public)

1. Introduction

- 1.1 This document sets out Celgene's response to the information requested by the ACCC in Attachment A of its letter dated 6 June 2022 (**ACCC RFI**).
- 1.2 Defined terms in this document have the same meaning as set out in the application for authorisation dated 3 December 2021.
- 1.3 The matters set out below are supported by the declaration of Prudence Smith dated 15 June 2022.

2. Celgene's Response

2.1 Questions 1 – 4 and 7 of the ACCC RFI are as follows:

1. [Confidential to Celgene].

2. [Confidential to Celgene].

3. [Confidential to Celgene].

4. [Confidential to Celgene].

7. [Confidential to Celgene].

- 2.2 Celgene provides its response to these questions on the basis that they relate to Celgene's agreements and conduct in Australia.
- 2.3 Celgene notes that the reason provided for each of the above requests for information is that the ACCC is "*uncertain about the nature of generic competition that may occur without the Proposed Conduct*".
- 2.4 Celgene understands therefore that the ACCC seeks to understand the nature and extent of competition which might exist without the Proposed Conduct **[Confidential to Natco/Juno]**.
- 2.5 Celgene notes that a number of the matters raised by the ACCC clearly have no bearing on the nature and extent of competition including the **[Confidential to Celgene]**.
- 2.6 Furthermore, Celgene is not in a position to provide the ACCC with information that would enable the ACCC to make an assessment of the nature and extent of competition which might exist without the Proposed Conduct, including **[Confidential to Celgene]**.
- 2.7 **[Confidential to Celgene]**. Celgene is not in possession of such information from generics

and accordingly any views expressed by it would be mere speculation.

2.8 In any event, Celgene considers that the information sought by way of responses to the above questions is not necessary to assess the Application, whether from the perspective of understanding the nature of generic competition, or otherwise.

2.9 Rather, as set out in Celgene's response to the Draft Determination, **[Confidential to Celgene]**, the evidence provided by Celgene, in particular the statutory declarations of Ms Smith dated 4 May 2022 and Mr O'Toole dated 29 April 2022 provide sufficient information to the ACCC regarding the nature of the generic competition (with and) without the Proposed Conduct based on which the ACCC is clearly able to be satisfied that benefits to the public are likely to arise from the Proposed Conduct without any likely detriment to the public.

2.10 This is because:

(a) **[Confidential to Celgene]**

(b) **[Confidential to Celgene]**

2.11 Celgene however is in a position to disclose the following information in response to the above questions, correct as at the date of this response:

(a) **[Confidential to Celgene];**

(b) **[Confidential to Celgene];**

(c) **[Confidential to Celgene];**

(d) **[Confidential to Celgene];**

(e) **[Confidential to Celgene].**

2.12 Celgene notes that the ARTG contains publicly available information as to which generic manufacturers are the sponsors of approved generic lenalidomide and pomalidomide products. It is open to the ACCC to contact these sponsors. Celgene reiterates that as set out in paragraphs 2.5 to 2.7 above, it does not consider such information to have any bearing on the Application nor is Celgene in a position to provide such information.

2.13 Question 5 of the ACCC RFI is as follows:

5. [Confidential to Celgene]

2.14 We understand that the ACCC is seeking to understand **[Confidential to Celgene]**.

2.15 Question 6 of the ACCC RFI is as follows:

6. [Confidential to Celgene], and in circumstances where there is [Confidential to the Applicants]; please advise whether or not you still consider that an alternative settlement could not be reached in the counterfactual, and why this is the case?

2.16 **[Confidential to Celgene].**

Commonwealth of Australia
STATUTORY DECLARATION
Statutory Declarations Act 1959

The following colour coding denotes confidential information and the associated disclosure restrictions:

Green

is confidential to Celgene (not to be shared with Natco/Juno or the public)

¹ Insert the name, address and occupation of person making the declaration

I, Prudence Jane Smith, of Level 41, 88 Phillip Street, in the state of New South Wales, solicitor, make the following declaration under the *Statutory Declarations Act 1959* (Cth):

² Set out matter declared to in numbered paragraphs

1. I have made one other declaration in connection with the Authorisation Application, declared on 4 May 2022 (my **First Declaration**). Unless otherwise stated, the capitalised terms and abbreviations used throughout this declaration have the same meanings as they do in my First Declaration.
2. Unless I expressly state to the contrary, I have not been instructed to waive legal professional privilege over any communications passing between me or Jones Day and Celgene (or its parent company, Bristol Myers Squibb) or third parties and I do not intend to do so by means of this declaration.
3. I make this declaration from my own knowledge, unless stated otherwise. Where I refer in this declaration to being informed of matters, I believe those matters to be true. I understand the importance of the ACCC being provided with true and accurate information.
4. In making this declaration I do so as an officer of the Court. I am also aware of the consequences of an authorisation granted on the basis of evidence or information that was false or misleading in a material particular under section 91B(3) of the *Competition and Consumer Act 2010* (Cth) and the repercussions of making a false or misleading statement to a Commonwealth Officer under section 90B of the *Crimes Act 1914* (Cth).

Lenalidomide and pomalidomide

I am instructed by Celgene of the following matters:

[Redacted content]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

I understand that a person who intentionally makes a false statement in a statutory declaration is guilty of an offence under section 11 of the Statutory Declarations Act 1959, and I believe that the statements in this declaration are true in every particular.

3 *Signature of person making the declaration*

[Redacted signature area]

4 *[Optional: email address and/or telephone number of person making the declaration]*

5 Place
6 Day
7 Month and year

Declared at Sydney, NSW on the 15th of June 2022

Before me,

8 Signature of person before whom the declaration is made (see over)



9 Full name, qualification and address of person before whom the declaration is made (in printed letters)

Samin Raihan
Legal Practitioner
Aurora Place
Level 41, 88 Phillip Street
Sydney, NSW 2000 Australia

10 Email address and/or telephone number of person before whom the declaration is made



This declaration was made in accordance with the *Coronavirus Economic Response Package (Modifications – Statutory Declarations and Notices of Intention to Marry) Determination 2021*

Note 1 A person who intentionally makes a false statement in a statutory declaration is guilty of an offence, the punishment for which is imprisonment for a term of 4 years — see section 11 of the *Statutory Declarations Act 1959*.

Note 2 Chapter 2 of the *Criminal Code* applies to all offences against the *Statutory Declarations Act 1959* — see section 5A of the *Statutory Declarations Act 1959*.

A statutory declaration under the *Statutory Declarations Act 1959* may be made before—

(1) a person who is currently licensed or registered under a law to practise in one of the following occupations:

Architect	Chiropractor	Dentist
Financial adviser	Financial Planner	Legal practitioner
Medical practitioner 1958	Midwife	Migration agent registered under Division 3 of Part 3 of the <i>Migration Act</i>
Nurse	Occupational therapist	Optometrist
Patent attorney	Pharmacist	Physiotherapist
Psychologist	Trade marks attorney	Veterinary surgeon

(2) a person who is enrolled on the roll of the Supreme Court of a State or Territory, or the High Court of Australia, as a legal practitioner (however described); or

(3) a person who is in the following list:

Accountant who is:

- a) a fellow of the National Tax Accountants' Association; or
- b) a member of any of the following:
 - i. Chartered Accountants Australia and New Zealand;
 - ii. the Association of Taxation and Management Accountants;
 - iii. CPA Australia;
 - iv. the Institute of Public Accountants

Agent of the Australian Postal Corporation who is in charge of an office supplying postal services to the public

APS employee engaged on an ongoing basis with 5 or more years of continuous service who is not specified in another item in this list

Australian Consular Officer or Australian Diplomatic Officer (within the meaning of the *Consular Fees Act 1955*)

Bailiff

Bank officer with 5 or more continuous years of service

Building society officer with 5 or more years of continuous service

Chief executive officer of a Commonwealth court

Clerk of a court

Commissioner for Affidavits

Commissioner for Declarations

Credit union officer with 5 or more years of continuous service

Employee of a Commonwealth authority engaged on a permanent basis with 5 or more years of continuous service who is not specified in another item in this list

Employee of the Australian Trade and Investment Commission who is:

- (a) in a country or place outside Australia; and
- (b) authorised under paragraph 3 (d) of the *Consular Fees Act 1955*; and
- (c) exercising the employee's function at that place

Employee of the Commonwealth who is:

- (a) at a place outside Australia; and
- (b) authorised under paragraph 3 (c) of the *Consular Fees Act 1955*; and
- (c) exercising the employee's function at that place

Engineer who is:

- a) a member of Engineers Australia, other than at the grade of student; or
- b) a Registered Professional Engineer of Professionals Australia; or
- c) registered as an engineer under a law of the Commonwealth, a State or Territory; or
- d) registered on the National Engineering Register by Engineers Australia

Finance company officer with 5 or more years of continuous service

Holder of a statutory office not specified in another item in this list

Judge

Justice of the Peace

Magistrate

Marriage celebrant registered under Subdivision C of Division 1 of Part IV of the *Marriage Act 1961*

Master of a court

Member of the Australian Defence Force who is:

- a) an officer
- b) a non-commissioned officer within the meaning of the *Defence Force Discipline Act 1982* with 5 or more years of continuous service
- c) a warrant officer within the meaning of that Act

Member of the Australasian Institute of Mining and Metallurgy

Member of the Governance Institute of Australia Ltd

Member of:

- a) the Parliament of the Commonwealth
- b) the Parliament of a State
- c) a Territory legislature
- d) a local government authority

Minister of religion registered under Subdivision A of Division 1 of Part IV of the *Marriage Act 1961*

Notary public, including a notary public (however described) exercising functions at a place outside

- a) the Commonwealth
- b) the external Territories of the Commonwealth

Permanent employee of the Australian Postal Corporation with 5 or more years of continuous service who is employed in an office providing postal services to the public

Permanent employee of

- a) a State or Territory or a State or Territory authority
- b) a local government authority

with 5 or more years of continuous service, other than such an employee who is specified in another item of this list

Person before whom a statutory declaration may be made under the law of the State or Territory in which the declaration is made

Police officer

Registrar, or Deputy Registrar, of a court

Senior executive employee of a Commonwealth authority

Senior executive employee of a State or Territory

SES employee of the Commonwealth

Sheriff

Sheriff's officer

Teacher employed on a permanent full-time or part-time basis at a school or tertiary education institution