

SCHEDULE 3 OFFICIAL ORDER

Official Order number TGA2016-325

1. Context

This Official Order is issued and agreed pursuant to and subject to the terms and conditions of the Deed between Finance and KPMG dated 11 November 2015.

2. Ordered Services

The provision of economic modelling and financial quantification of the regulatory, social and economic impacts of the proposed regulatory options for the rescheduling of Codeine as outlined in the Department of Health request for quote and statement of requirements and with the response provided by KPMG.

A report that covers all the elements of the request for quote and the statement of requirement, and is fit for purpose to support the drafting of the Codeine RIS will be provided by 31 August 2016.

3. Policies, Standards and Guidelines

Adhere to the standards and requirements of the Office of Best Practice Regulation (OBPR) using the Regulatory Burden Measurement Framework (or other suitable methodologies as agreed by OBPR and the TGA).

4. Required Contract Material

Final Report

5. Commencement and Time frame

Contract Commencement Date:

2 August 2016

Time frame:

To be completed by 31 August 2016

6. Specified Personnel

Nil

7. Fees, allowances and costs

An invoice must be submitted within 20 Business Days of completing the Ordered Services.

\$199,163 (GST inclusive) for the 4 week project with provision of suitable final report

Up to \$10,000 (GST inclusive) to cover travel and associated costs where prior approval has been granted by TGA.

8. Existing Material

None specified

9. Commonwealth Material

The TGA may provide:

- Industry/public submissions (to the extent they can be shared noting confidentiality provision) and any summaries/analysis conducted by the TGA on these submissions;
- relevant ACMS Committee papers;
- a Microsoft Excel version of the current ARTG;
- other papers on economic and social impact of codeine use;
- list of internal contacts and key regulatory staff;
- list of any recent regulatory changes which have impacted labelling, dosage and distribution requirement for medicines other than codeine and the associated RISs;
- data (if obtainable) from the trial conducted by the Pharmacy Guild of Australia in relation to real-time recording and monitoring of the purchase of codeine-containing medicines from pharmacies (specifically this will provide volumes of sale).

Any other material that the Service Provider requests throughout the contract period as agreed to by TGA.

10. Security and privacy

No additional security required

11. Service Provider's Confidential Information

(a) Contract Provisions/Schedules/Attachments

Item	Period of Confidentiality
none specified	

(b) Contract-related material

Item	Period of Confidentiality
none specified	

12. Special Conditions

Condition	Clause of Deed Affected (if any)
None specified	

Signed for and on behalf of the Commonwealth of Australia, represented by Health by:

[Redacted Name]

^Name^
Health's Representative

[Redacted Signature]

.....
2/8/16
Date

Signed for and on behalf of the Service Provider by:

[Redacted Name]

.....
^Name^
Service Provider's Representative

[Redacted Signature]

.....
Signature

02/08/2016

.....
Date