

Biosimilar Education Grant Opportunity Guidelines

Commonwealth policy entity:	Department of Health
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Enquiries:	If you have any questions, please contact Grant.ATM@health.gov.au or (02) 6289 5600 Questions should be sent no later than 12pm Canberra local time 9 March 2018
Close:	2pm Canberra local time 16 March 2018
Type of Grant Opportunity	One off ad-hoc process

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1. Biosimilar Education Grant opportunity overview and objectives

The Biosimilar Education grant opportunity aims to increase confidence in the use of biosimilar brands of biological medicines that are listed on the Pharmaceutical Benefits Scheme (PBS). Through the increased use of biosimilar medicines, the program objective is to support a competitive market for biological medicines and as a result provide:

- Cost savings to the PBS that can be reinvested in the health system. The savings will flow from market competition on price, and related reductions in the PBS subsidised price under the PBS price disclosure arrangements;
- Protect against medicines shortages, which are an increasing issue worldwide; and
- Increase prescriber and consumer choice.

The total value of the fund is \$5 million (GST exclusive) available over 4 financial years (2018/19-20/21) for the Biosimilar Education Grant Opportunity. The activities contribute to the achievement of the Department of Health (the department)'s *Portfolio Budget Statement Outcome 4.3 - Pharmaceutical Benefits, Individual Health Benefits Outcome (Outcome 4)* by providing access to cost-effective, high quality medicines to all eligible Australians, through the subsidisation of the cost of medicines through the PBS.

2. Outcomes

The expected outcomes of the grant activity are to provide education to increase confidence in, and the use of biosimilar medicines, through:

- Raising health care professionals' and consumer awareness of the growing availability of biosimilar medicines and the important role biosimilar medicines can play in Australia's healthcare system.
- Building health care professionals' and consumer understanding of biosimilar medicines and the scientific/regulatory processes that underlie their development and approval.
- Establishing and sharing the current evidence base with health care professionals with the aim of filling knowledge/data gaps, addressing clinical uncertainties and guiding the integration of biosimilar medicines into day-to-day clinical practice.
- Identifying and supporting experts to provide evidence-based factual information about biological medicines, and in particular biosimilars, to health care providers and consumers.
- Developing and disseminating materials and resources about biological medicines, and in particular biosimilar medicines, including through both print and electronic communications to health care providers and consumers.
- Developing Continuing Professional Development (CPD) online resources and events about biological medicines, and in particular biosimilar medicines, for health care providers.

- Undertaking evaluation and reporting activities in relation to the impact of education and uptake activities concerning acceptance and use of biosimilar medicines (for example market research on impact of educational activities, data collection, analysis and reporting).

This is a new grant opportunity with new activities to complement and extend the activities undertaken by the department through the Biosimilar Awareness Initiative.

The successful organisation is expected to work collaboratively with other stakeholders including other peak industry bodies and peak bodies for clinician prescribers, pharmacy, consumers, and with specialist quality use of medicines education providers. This collaboration is expected throughout all aspects of delivering the grant with active consultation through the design, implementation and evaluation of all funded activities.

The grant will be undertaken in accordance with the [Commonwealth Grants Rules and Guidelines \(CGRGs\)](#).

3. Grant selection process

This grant opportunity has been established as a one-off or ad hoc grant. The department considers that this is an appropriate type of selection process considering the specialist nature of the grant activity.

4. Eligibility

The department has determined that the Generic and Biosimilar Medicines Association (GBMA) is the only organisation eligible to apply under this activity, due to GBMA's role within the market place, and alignment with the policy framework for the activities required.

4.1 Eligible grant activities

Activities funded under this opportunity must be consistent with the objectives and outcomes in Section 1 and 2 of these guidelines. The grant can be used for the following grant activities:

- Awareness activities including conference presence and presentations, meeting/webinars, e-learning modules, formal Continuing Professional Development accredited activities for health professionals, development and distribution of educational pieces for publications and other distribution, international speaker visits and electronic resources (website, newsletter, and practical tools for pharmacists and other health care providers).
- Activities to establish and share the current evidence base including collection and analysis of data, development of an evidence compendium, reflective practice/clinical update review articles and quantitative research.
- Evaluation and reporting activities on the impact of education and uptake activities including market research, data collection, analysis and reporting.

It is expected that funding will be made in quarterly instalments to the limits detailed in table 4.1.1 below.

Table 4.1.1 – Grant Funding

2017-18 \$m (GST exc.)	2018-19 \$m (GST exc.)	2019-20 \$m (GST exc.)	2020-21 \$m (GST exc.)	Total \$m (GST exc.)
\$485,000	\$1,780,000	\$1,860,000	\$875,000	\$5,000,000

Submitting an application does not guarantee that you will receive funding.

Costs that the grant can be used for:

- Operational support including administration and staff expenses up to 10% of the grant;
- Salary for an approved Project Manager to implement the activity;
- Education and awareness resources and activities, supporting research and data collection activities;
- Collaboration with other relevant organisations; and
- Evaluation of activities and initiatives.

It is expected that, unless approved in writing by the department, all employee and contractor travel costs will align with the Australian Governments whole-of-government policies for travel (further details are available from the [Department of Finance](#)).

The Project Manager position is a required position. The person occupying this position must be approved by the department. It is expected that the person who fills this position will have relevant industry expertise and skills in program management and communication or education.

4.2 Ineligible grant activities

The following types of activities will not be funded under this opportunity unless approved in writing by the department (or other specified grant manager):

- Ongoing annual subscriptions to publications and software; and
- Ongoing operating (recurrent) costs including rent, utilities, maintenance and insurance.

In addition:

- Expenditure should not go beyond 31 December 2020; and
- Expenditure should not be committed if it has not been approved in the annual activity plan and budget.

5. The assessment criteria

The proposal is required to provide sufficient information to allow the assessment criteria to be evaluated:

CRITERION 1: Alignment with Program Objectives

CRITERION 2: Organisational Capacity and Performance

CRITERION 3: Efficient and Effective Use Of Grant Funds

CRITERION 4: Stakeholder Engagement

You are also required to provide:

- An Activity work plan;
- Communication Strategy;
- An indicative budget; and
- A risk management plan.

Details will be included in the Application Form.

6. Grant assessment and decision making

The application will be assessed by a department assessment committee. The department may seek information from any other source, including from within the Commonwealth, whether or not the individuals or organisations contacted are nominated as referees.

Descriptive Classification Scoring Method

A Descriptive Classification Scoring Method has been selected as the most appropriate scoring methodology for this Grant Opportunity.

Table 6.1.1: Descriptive Classification Rating Scale

Rating (for individual criterion)	Rank
High quality – response to this criterion addresses all or most sub-criteria to a higher than average standard. Evidence is demonstrated and confirms good performance against this criterion.	Highly Suitable
Good quality – response against this criterion meets most sub-criteria to an average and acceptable level. Some evidence is demonstrated and provides some support for claims against this criterion.	Suitable
Poor quality – poor claims against this criterion, meets some or none of the sub-criteria. Evidence is not demonstrated, not relevant or lacking in detail.	Not Suitable

An assessment of value with relevant money will also be undertaken on the proposal, and include such considerations as:

- the funding proposal meeting the objectives as outlined in the Grant Opportunity Guidelines;
- the amount of funding being requested in the funding proposal being commensurate with the scale of the project/activities being undertaken;
- whether there is demonstrated history of delivery of similar activities; and
- Whether the proposal (grant) is likely to add value by achieving something worthwhile that would not occur without grant funding.

The application will be assessed against the selection criteria and that the proposal represents value for money.

7. Who will approve the grant?

Following assessment, the assessment committee will make recommendations to the Decision Maker. The Decision Maker for this Grant Opportunity is Assistant Secretary, Pricing and PBS Policy Branch, Technology Assessment and Access Division. The Decision Maker will make the final decision to approve a grant.

The Decision Maker's decision is final in all matters, including:

- the approval of the grant;
- the grant funding amount to be awarded; and
- the terms and conditions of the grant.

The Decision Maker must not approve funding if they reasonably consider the program funding available across financial years will not accommodate the funding offer, and/or if the application does not represent value with money.

There is no appeal mechanism for decisions to approve or not approve a grant.

8. Notification of application outcomes

The applicant will be advised of the outcome in writing, following a decision by the Decision Maker. If the applicant is successful, the advice will contain details of any specific conditions attached to the grant.

8.1 The grant agreement

The successful applicant must enter into a legally binding grant agreement with the Commonwealth represented by the department. The department will use the [Commonwealth Standard Grant Agreement](#). [Commonwealth General Grant Conditions](#) for the grant agreement will apply and cannot be changed. A schedule may be used to outline the specific grant requirements. Any additional conditions attached to the grant will be identified in the grant offer or during the grant agreement negotiations.

The successful applicant will be required to:

- Maintain contact with the department and advise of any emerging issues that may impact on the success of the activity;
- Engage a market research firm to provide a Report at the end of the grant period on the combined impact of Biosimilar Education grant activities and the Biosimilar Awareness Initiative, updating the research by the Department of Health undertaken at the beginning of the Biosimilar Awareness Initiative;
- Seek the Department of Health's approval for core messaging to be used in program materials prior to publication; and provide copies of, or links to, all proposed materials prior to publication or use at events; and
- Comply with all relevant codes of conduct.

The department will negotiate an agreement with the successful applicant by early April 2018. If there are unreasonable delays in finalising a grant agreement, the grant offer may be withdrawn.

Where a grantee fails to meet the obligations of the grant agreement, the department may terminate the agreement.

The applicant will not be considered successful and should not make financial commitments in expectation of receiving funding until a funding agreement has been executed with the Commonwealth.

9. Announcement of grants

Grants awarded will be listed on the GrantConnect website 21 working days after the date of effect as required by Section 5.3 of the *CGRGs*.

10. Grant acquittal and reporting

The grantee must submit reports in line with the timeframes in the grant agreement. Reports will include:

- Quarterly Performance Report outlining progress against the objectives and outcomes of the grant including against the Communications strategy, approved Annual Activity Work Plan, and providing details of stakeholder participation.
- Quarterly financial updates, and Annual financial acquittal report against the approved Budget;
- A detailed Final Report.

11. Grant evaluation

The department will evaluate the Biosimilar Education grant program to measure how well the outcomes and objectives have been achieved. Your grant agreement requires you to provide information to help with this evaluation.