Australian Government
Department of Health

BIOSIMILAR AWARENESS INITIATIVE

PROJECT MANAGEMENT PLAN

Date: June 2016

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1 PROJECT DEFINITION

PROJECT BRIEF

In May 2015 the Minister for Health, Sussan Ley announced the government's Pharmaceutical Benefits Scheme (PBS) Access and Sustainability Package. The reforms followed consultations and negotiations across the pharmaceutical supply chain including consumers, pharmacists, medicine manufacturers, wholesalers and doctors.

As part of the package, funding of $20 million has been committed over three years (2015-16 to 2017-18) to undertake awareness and education activities. These are intended to support awareness of, and confidence in, biosimilar medicines.

BACKGROUND

Biologic and Biosimilar Medicines in Australia

Biologic medicines have become increasingly popular in the last decade to treat conditions like arthritis. This is reflected in the PBS, where biologic medicines have grown from about 4 per cent of the PBS budget 10 years ago, to about 25 per cent today.

Australia was one of the earliest countries to establish processes for the regulation of biosimilar medicines, in 2008. Aczicrit® and Grandicrit® (epoetin lambda) were the first products approved in Australia as biosimilars in 2010.

The complexity of the conditions that can be treated with biologic medicines and the specialist nature of the condition treated means that the bulk of these medicines are currently prescribed in a hospital setting. However, community pharmacies are increasingly becoming involved in supply of these medicines.

Increasing numbers of submissions for these medicines are seeking listing on the PBS. The Pharmaceutical Benefits Advisory Committee (PBAC) considered applications for biosimilar medicines at its March 2015, July 2015, March 2016 and July 2016 meetings, and this trend is expected to continue.

The availability of biosimilar medicines creates choice and competition. With multiple brands available, the prescriber, patient and pharmacist have options and the competition can lead to lower prices.

PROJECT OBJECTIVES & OUTCOMES

The aim of the Biosimilar Awareness Initiative (the Initiative) is to improve awareness of, and confidence in the use of biosimilar medicines for healthcare professionals and consumers.

The Projects Key Objectives are to:

- improve the overall awareness of the PBS and the future potential of biologic and biosimilar medicines across the community;
- communicate to stakeholders the benefits and information required to overcome barriers to the use of biosimilar medicines;
- supporting and maintaining patient choice, by improving understanding of the medicines used by patients and their families;
- providing education and/or refreshing previous education to support healthcare professionals to meet the clinical and information needs of their patients with regard to both prescribing and dispensing the medicines; and
- supporting the specific communication and information needs of stakeholders, including the PBAC, at times when a particular medicine is being considered and or recommended for listing on the PBS, especially where brand substitution may apply.

OUT OF SCOPE

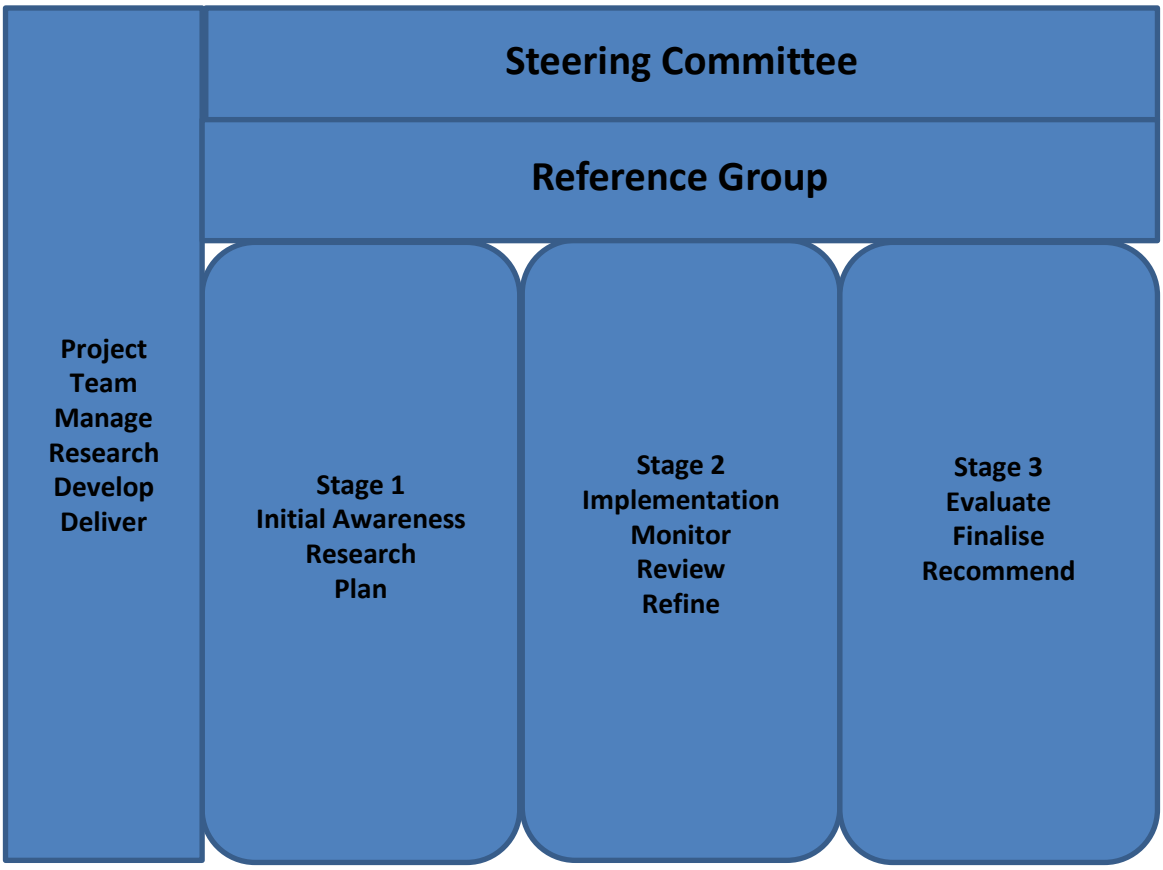
The following are outside the scope of the project:

- the process for determining whether a medicine is a biosimilar;
- the regulatory and/or assessment processes used by the Therapeutic Goods Administration (TGA) to consider the registration of medicines, including biosimilar medicines;
- the assessment processes used by the PBAC to assess medicines, including biosimilar medicines, for recommended listing on the PBS; or
- any approaches to attract manufacturers of biologic and biosimilar medicines to Australia.

2 PROJECT PLAN

PROJECT MANAGEMENT STAGES

This project has a life span of 3 years ending in June 2018 with Stage 1 due to be completed in 2016. The following diagram provides an overview of the current Project Stages.



The Initiative has in place robust project management methodologies to maintain and ensure the quality of this project.

COMMUNICATIONS STRATEGY

Purpose

The Communication Strategy contains the description of the means and frequency of communication to stakeholders internal and external to the project. It facilitates engagement with stakeholders through the establishment of a controlled and bi-directional flow of information.

Communication Objectives

The objectives of the communication strategy are:

- To raise awareness and understanding of biosimilar medicines.
- To increase the confidence of healthcare professionals and patients to consider and use biosimilars.
- To raise awareness and understanding about the PBS and the role of the PBAC in evaluating and listing biosimilar medicines.
- To engage with key stakeholders and harness support for the project.

Stakeholder Identification and Engagement Plan

Effective stakeholder identification and engagement is an iterative process critical to the success of the Initiative. For a detailed update of this plan refer to attachment A.

Core Themes

Having undertaken extensive research and consulted with experts, the following key information needs have been identified.

Definition: Some medicines are made from biological sources. Once the patent on the first brand of the biologic medicine expires, copies can be made. These are called biosimilar medicines.

Biologic and biosimilar medicines are subject to rigorous checks and balances before approval: Biologic medicines are made in a sterile facility and checked by experts. The Therapeutic Goods Administration (TGA) and the Pharmaceutical Benefits Advisory Committee (PBAC) evaluate medicines before they can be used in Australia or subsidised through the Pharmaceutical Benefits Schedule (PBS). Biologic and biosimilar medicines are prescribed by health care professionals and once on the market, these medicines are monitored as are all other prescription medicines in Australia.

Australia has positive experience using these medicines: Biologic medicines improve people's lives. Biosimilar medicines are part of the success. Australians have been using them for more than 10 years.

Medicine substitution is a patient and prescriber choice: When multiple brands are available you have an opportunity to choose the brand of biologic medicine that you take. You and your prescriber have the option to decide whether or not you should receive a particular brand, if not, your pharmacist can offer you the choice. Your pharmacist cannot dispense a different brand without your knowledge.

Biosimilar medicines can result in market competition, reduced cost and greater access to more medicines for more people: Biosimilar medicines encourage market competition which leads to reduced costs. This will result in a more sustainable PBS and greater access to a wider range of treatments for more consumers.

These themes highlight the main topics where information will support a better understanding of these medicines and their use. Other themes may also be necessary however this list outlines the main areas of interest.The core themes will be confirmed pending feedback from the Reference Group, Pharmaceutical Benefits Advisory Committee, Therapeutic Goods Administration and Steering Committee.

Attachment B illustrates the processes and procedures to be undertaken to identify, create, review and communicate key message content within the project.

Communication Channels

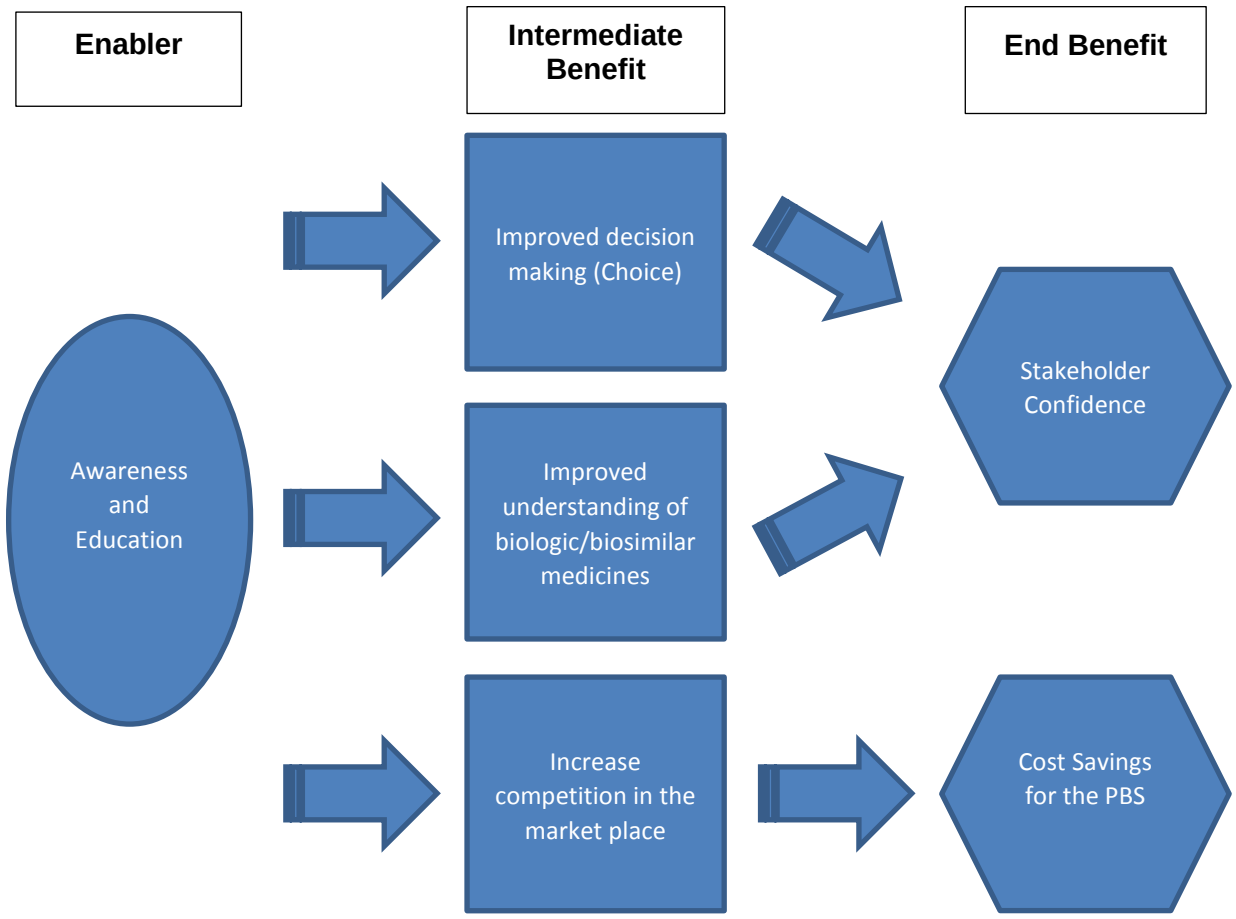
All communication material will be made available through Department of Health's website. The following communication channels will be considered;

- fact sheets and FAQs
- brochure
- accredited education/training module (online)
- articles in medical/pharmacy journals and industry association newsletters
- information on Health's and pharmacy organisations' websites
- online videos
- broadcast emails from Health

PROJECT EVALUATION

The primary objective of stage 3 of the Initiative is to evaluate the effectiveness of the Initiative against the key performance indicators (KPIs).

The following diagram depicts the flow on of the project's benefits:



An evaluation plan for the above benefits is set out in the following table:

Benefit Evaluation Plan		
Benefit	**KPI**	**Measurement Method**
Awareness and Education	% of Stakeholder Awareness	Stakeholder Survey
Increase Competition	% Biosimilar Medicine Prescriptions	PBS dispensing data
	% Switching between reference biologic and biosimilar medicine	PBS dispensing data
PBS Cost Savings	Savings of up to $880m (2015-2020)	PBS expenditure data*

* where available, incorporate data received from states and territories on biosimilar medicine usage in hospital settings.

ATTACHMENT A – STAKEHOLDER IDENTIFICATION AND ANALYSIS

The Biosimilar Awareness Initiative team conducted an analysis of groups and individuals who hold a stake in the successful outcome of the Initiative. This analysis has been used to inform further refinement of the communication strategy. The refined communications strategy will help the Initiative to ensure core themes can be delivered clearly and consistently; ensuring that they are suitably tailored to their audience.

Identification

The stakeholder analysis identified a range of relevant stakeholders, including those with whom the Initiative was already engaged. Stakeholders were identified through: previous engagements; horizon scanning to predict possible impacts of emerging biosimilar medicines; and the stakeholder's ability to impact the success of the Initiative. Stakeholders were grouped into those with similar interests for the purpose of engagement strategies.

Evaluation

Using the established register of stakeholders the impact of each stakeholder was assessed. Several factors were considered, including current position statement, size of member base, their ability to influence the Initiative's objectives, and previous engagements with the Department.

Follow Up

This register of stakeholders allows the Initiative to take a structured approach to engagement with groups who can significantly influence the Initiative and who can benefit from it the most.

One of the outcomes from this re-assessment of the stakeholders is that the membership of the Reference Group has been revised. The new members of the committee are reflective of the exposure that these groups have had in the use of biologic medicines.

This register will also be used to ensure that the core themes are delivered in a manner that is tailored to the specific needs of stakeholders. By working collaboratively and in partnership with our stakeholders this will ensure that the Initiative will deliver the communication strategy in a clear, relevant and consistent manner.

ATTACHMENT B: PROCEDURE FOR KEY MESSAGES/CONTENT