Biosimilars Awareness Initiative Reference Group Communiqué

The third meeting of the Biosimilars Awareness Initiative Reference Group was held in Canberra on 18 August 2016.

Attendees

The Chair of the meeting was Dr Anthony Hobbs. Attendees included: representatives from the Pharmaceutical Benefits Advisory Committee; Arthritis Australia; Australian Rheumatology Association; Crohn's and Colitis Australia; Gastroenterological Society of Australia; Generic and Biosimilar Medicines Association; Medicines Australia; NPS MedicineWise; Pharmaceutical Society of Australia; Royal Australasian College of Physicians; Society of Hospital Pharmacists of Australia; Haematology Society of Australia and New Zealand and The Pharmacy Guild of Australia. Representatives of the Department of Health were also in attendance.

Purpose

The meeting provided an opportunity for Reference Group members to review the progress of the Initiative, including the:

- Updated project plan;
- Final report of the literature review; and
- Core communication themes and the communication plan.

The Reference Group members provided feedback on the Initiative and provided advice on the type, form, content and target audiences of communication materials to be considered under the Initiative.

The meeting also included an update on naming conventions for biologic medicines provided by a representative from the Therapeutic Goods Administration (TGA).

Outcomes

Project Plan Presentation

The Initiative is adopting best practice project management procedures to ensure the communications products and materials are consistent and appropriately targeted. In order to achieve this, a comprehensive project management plan has been developed and endorsed by the Steering Committee.

A high-level summary of the project plan was presented. It was noted that phase one of the project, incorporating the evidence-base and research for the work, is nearing completion,

and the project team has commenced the planning and development of the communication products for early concept testing. Reference Group members were asked to support and disseminate the plan to their respective organisations.

Literature Review Discussion

Reference Group members were provided with a copy of the *Literature Review of International Biosimilar Medicines Final Report* prepared on behalf of the Department by Dr Michael Ward, Dr Stephanie Reuter Lange and Dr Kirsten Staff, PhD, from the University of South Australia. Members were requested to review the report and to consider the potential learnings arising from the report for the Initiative.

Dr Ward provided a presentation on the review, incorporating four themes of regulation, uptake, outcomes and perceptions around the use of biosimilars.

TGA Presentation on Naming Conventions

The TGA representative provided a presentation on the International Non-proprietary Names (INN) Expert Committee, including an update on naming conventions regarding biologic medicines. This included an overview of the proposed Biological Qualifier (BQ) Scheme. The BQ Scheme was adopted by the World Health Organisation (WHO) on 28 July 2016. TGA is still considering the issue and is yet to decide on the BQ Scheme. The TGA representative advised that the European Medicines Agency and the US Food and Drugs Administration are currently considering their approaches to this issue.

Communications Plan and Core Themes Update

Reference Group members reviewed the plan's core communication themes which have been developed as a central component of the communications strategy of the Initiative. Members were requested to identify any gaps and opportunities, and to provide comment on the effectiveness of the plan's core communication themes in addressing the information needs of stakeholders with regards to the use of biosimilars in Australia.

The Department of Health's Communication Division team provided an overview of the plan's methodology which is based on behavioural economics principles. The process to understand the nature of the issues and the needs of each of the target audiences is evidence driven. The strategy developed is based on identifying needs, stakeholder perspectives and the information required now and throughout the development, and roll-out will incorporate continual testing for implementation success. Members noted a presentation about the Department's general approach to health promotion, and considered some of the specific issues relating to biologic and biosimilar medicines.

Next Meeting of the Reference Group – To be confirmed.