Biosimilars Awareness Initiative Reference Group Communiqué

The second meeting of the Biosimilars Awareness Initiative Reference Group was held in Canberra on 12 May 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; Consumers' Health Forum; 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; and The Pharmacy Guild of Australia. Representatives of the Department of Health were also in attendance.

Purpose

The meeting was an opportunity for the Reference Group members to gain a greater understanding of the:

- current awareness of biosimilars amongst relevant stakeholder groups;
- Pharmaceutical Benefits Advisory Committee processes;
- Therapeutic Goods Administration's regulatory processes; and
- current Pharmaceutical Benefits Scheme data collection options available.

The meeting was also an opportunity for Reference Group members to provide feedback on the qualitative market research conducted by ORC International and to provide advice on the type, form, content and target audiences of communications materials to be developed by the Initiative.

Outcomes

Market Research

The discussion at the meeting largely focused on the market research findings and how this data can be used to inform the development of communication and education materials for the Initiative. The research provides valuable insights into the identification of key target groups and the reassurances that these groups are seeking with respect to biosimilars.

It was agreed that a summary of the market research and the presentation would be made available on the PBS website.

The members discussed the importance of developing consistent messages to be delivered to all stakeholders. It was highlighted during discussions that despite messages to various stakeholders needing to be of differing levels of complexity, the

underlying message must remain consistent if there is to be significant gains in the understanding of biosimilars.

It was agreed that important key points that need to be highlighted through the Awareness Initiative include:

- patient and prescriber choice;
- how lower cost biosimilars are beneficial to the sustainability of the healthcare system;
- that lower cost medicines do not equate to inferior products;
- reiteration of the quality, safety and efficacy of biosimilar medicines; and
- that more affordable biosimilars may lead to an increase in treatment options available through the PBS.

The members discussed that the strategy will also need to consider the levels of general health literacy needed to support the understanding of the biosimilars message. This could include information on the PBS, how it works, including costs of medicines on the PBS and benefits to the community. It was seen as important that prescribers and dispensers are made aware of the financial impact that their choices may have on the healthcare system over time.

It was further agreed that healthcare professionals were the key group for targeted communications due to their role in clinical decision-making and patient education.

PBS Data Analysis

Reference Group members were provided with a presentation outlining the PBS data currently collected and existing analysis capabilities. Members expressed an interest in some of this analysis, including the distribution of general vs concessional patients and the uptake of biosimilars. This information will be provided to the Reference Group at the next meeting.

PBAC

Reference Group members were provided with a presentation outlining the role of the PBAC and that members are appointed by the Minister and include prescribers, health economists, pharmacists and consumer representatives.

The PBAC considers both cost effectiveness and relative clinical effectiveness of a medicine. A PBS listing can only be made if the medicine has been approved by TGA, in terms of safety and efficacy, and it is listed on the Australian Register of Therapeutic Goods. The TGA and PBAC have been trialling parallel processes with an aim to expediting the health technology assessment process. The decision to a-flag a biosimilar is made by PBAC on a case by case basis, upon considering the information that is available. In 2015/16 the PBS cost $9.7 billion. Biologics are the fastest growth area for PBS costs with medicines on patent growing at 11 per cent or $1.2 billion/annum.

More detailed information is available in the PBS Guidelines.

TGA

Reference Group members were provided with a presentation outlining the approvals process used by the TGA for biosimilars. The TGA emphasised that the principles guiding biosimilar regulation are shared by the European Medicines Agency, the US Food and Drug Administration, Health Canada, the TGA and many others. Australia has not received any applications for biosimilars that have not already been seen in Europe. Twenty-two biosimilar products have been approved by the European Medicines Agency; these have remained on the market.

Biosimilars cannot be considered to be identical to the originator biologic due to micro-heterogeneity and variations within the manufacturing processes; however, they are highly similar. In order for a biosimilar to be approved for use, the sponsor must be able to establish comparability to the reference product, including comparable safety and efficacy through clinical trials.

Next Meeting of the Reference Group will be in July 2016.