Biosimilar Awareness Initiative Reference Group Communiqué

The fifth meeting of the Biosimilar Awareness Initiative Reference Group was held in Canberra on 11 August 2017.

Attendees

The Chair of the meeting was Dr Anthony Hobbs. Attendees included: representatives from Arthritis Australia; the Australian Rheumatology Association; the Consumers' Health Forum of Australia; Crohn's and Colitis Australia; the Gastroenterological Society of Australia; Generic and Biosimilar Medicines Association; Medicines Australia; NPS MedicineWise; the Royal Australasian College of Physicians; the Society of Hospital Pharmacists of Australia; the Pharmacy Guild of Australia and the Therapeutic Goods Administration (TGA). Representatives of the Department of Health were also in attendance.

Purpose

The meeting provided an opportunity for Members to receive an update on regulatory assessment of biosimilar medicines from the TGA, and to discuss the progress of the Biosimilar Awareness Initiative (the Initiative), current issues around biosimilar medicines, and policy developments in the area of biosimilar uptake drivers. Members provided an update of the activities undertaken by their organisations in relation to increasing awareness of biosimilar medicines.

Outcomes

TGA Presentation on the evidential basis of marketing approval for biosimilars

Dr Michael Coory from the TGA presented on current aspects of regulatory assessment for biosimilar medicines. The presentation reflected on the sophisticated and robust assessment of biosimilars by major international regulatory bodies, reviewed the detailed evidentiary requirements, provided information about manufacturing changes for a number of reference biological medicines, and reflected on the confidence gained through the regulatory process and experience to date with biosimilars.

Other considerations impacting biosimilars were discussed, including post market pharmacovigilance. Dr Coory noted that routine pharmacovigilance is effective in Australia and has been in place for over 50 years. It was noted that global surveillance networks provide assurance that safety signals will be detected.

Initiative Update

The Department of Health provided an update on the dissemination of communications products and the development of education activities. The meeting was advised that information kits for healthcare professionals have been distributed to a number of stakeholders and have been provided for conferences at which biosimilar medicines are being discussed. Advice was provided on conference and webinar presentations, and development of a video animation focussing on biosimilars and generics. Stakeholders were encouraged to pursue further opportunities for dissemination of Initiative materials, available online or in hard copy. Updated Fact Sheets have been published to support PBS listing of a new infliximab biosimlar.

2017 Federal Budget measures to encourage uptake of biosimilar medicines

The Department of Health updated Members on the following initiatives announced as part of the Budget process in May 2017 to increase the uptake of biosimilar medicines:

1. encouraging prescribing of a biosimilar brand rather than the reference biological brand for treatment naïve patients; and
2. providing for a lower authority level for prescribing biosimilar brands (for example, streamlined authority required) while maintaining an existing higher level authority for the reference biological brand (for example, written authority).

These measures were agreed as part of the Strategic Agreements in place with Medicines Australia, the Generic and Biosimilar Medicines Association, and the Pharmacy Guild of Australia.

The Department of Health will consult broadly with stakeholders, including reference group members, on implementation approaches for biosimilar uptake drivers.

[Note: consultation occurred from late September 2017 to November 2017]

Next Meeting of the Reference Group –to be confirmed.