

Biosimilar Awareness Initiative Reference Group Communiqué

The fourth meeting of the Biosimilar Awareness Initiative Reference Group was held in Canberra on 29 November 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; Consumers' Health Forum and The Pharmacy Guild of Australia. Representatives of the Department of Health were also in attendance.

Guest presenters

Dr Paul Cornes, consultant paediatric oncologist at the Bristol Haematology & Oncology Centre (UK)

Dr Bronwen Harvey, Therapeutic Goods Administration (TGA)

Purpose

The meeting provided an opportunity for Members to review the progress of the Initiative. Members also heard presentations on pharmacovigilance processes in Australia and the experience of biosimilar medicines in Europe.

Outcomes

TGA Presentation on Pharmacovigilance in Australia

Dr Bronwen Harvey provided an overview of the pharmacovigilance activities conducted or overseen by the TGA. Members noted that some of the activities described involved close collaboration with the pharmaceutical industry specifically regarding risk management plans (RMPs) and review of periodic safety update reports (PSURs). The TGA also conducts regular and ad-hoc conferences with overseas regulators to discuss new trends and safety concerns.

Dr Harvey confirmed that no significant safety issues had been reported to date in relation to biosimilar medicines either internationally or in Australia.

Members sought information about whether or not the current naming convention for biological and biosimilar medicines present a challenge to pharmacovigilance activities. Dr Harvey noted that brand and batch number may not always be provided by the reporter within the spontaneous adverse drug reaction reporting system. Members discussed that prescribing, dispensing and reporting with both brand and active ingredient would assist with pharmacovigilance activities. It was noted that this is reflected in the third guiding principle within the CATAG document entitled "*Overseeing biosimilar use*".

Presentation on the International Experience of Biosimilar Medicines

Dr Paul Cornes provided a presentation about the experience of biosimilar medicines in Europe and more specifically in the UK. He highlighted the impact that the use of biosimilar medicines is having in controlling payer costs. Dr Cornes presented information on the trends towards increasing health technologies costs over time and discussed the importance of stewardship of scarce healthcare resources. He stated that the use of biosimilar medicines aligned with the World Health Organization's statement that the leading cause of inefficiency in healthcare is the use of more expensive versions of a drug where a suitable alternative is available.

Dr Cornes pointed to the growing evidence that biosimilar medicines carry no clinically meaningful differences in outcomes for patients, with proven similar safety, quality and efficacy profiles. Dr Cornes noted the large variance in uptake of the infliximab biosimilar between Australia and countries such as Denmark, with 96 per cent market share. He discussed various policy approaches used across the world to increase the uptake of biosimilar medicines.

Communication products update

The Department provided an update on the development of communications products. Members were thanked for their contribution to the revised website including the comprehensive frequently asked questions. The Department confirmed that independent concept testing of the communication products is underway through in-depth interviews and focus group testing.

Next Meeting of the Reference Group – To be confirmed.