Rheumatology Subcommittee of PTAC meeting
Meeting held 3 July 2014

(minutes for web publishing)

Rheumatology Subcommittee minutes are published in accordance with *the Terms of Reference for the Pharmacology and Therapeutics Advisory Committee (PTAC) and PTAC Subcommittees 2008.*

Note:

- that this document is not necessarily a complete record of the Rheumatology Subcommittee meeting; only the relevant portions of the minutes relating to Rheumatology Subcommittee discussions about an Application or PHARMAC staff proposal that contain a recommendation are generally published.

The Rheumatology Subcommittee may:

a) recommend that a pharmaceutical be listed by PHARMAC on the Pharmaceutical Schedule and the priority it gives to such a listing;
b) defer a final recommendation, and give reasons for the deferral (such as the supply of further information) and what is required before further review; or
c) recommend that PHARMAC decline to list a pharmaceutical on the Pharmaceutical Schedule.

These Subcommittee minutes were reviewed by PTAC at its meeting on 6 &7 November 2014, the record of which will be available in February 2015

Record of the Rheumatology Subcommittee of PTAC meeting held 3 July 2014

1 Biosimilar Infliximab

Application

1.1 The Subcommittee reviewed an application from Hospira (New Zealand) Ltd for the listing of its biosimilar infliximab (CT-P13, Inflectra/Remsima) in Section H of the Pharmaceutical Schedule.

Recommendation

1.2 The Subcommittee recommended that, subject to Medsafe approval, Hospira's biosimilar infliximab should be listed in Section H of the Pharmaceutical Schedule subject to the same restrictions as the Remicade (Janssen) brand of infliximab.

1.3 The Decision Criteria particularly relevant to this recommendation are: i)The health needs of all eligible people within New Zealand; (iii)The availability and suitability of existing medicines, therapeutic medical devices and related products and related things; (iv)The clinical benefits and risks of pharmaceuticals; (v)The cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health & disability support services; and (vi) the budgetary impact of any changes to the pharmaceutical schedule.

Discussion

1.4 The Subcommittee noted that PTAC and the Gastrointestinal Subcommittee of PTAC had previously reviewed the application to list Hospira's biosimilars infliximab. Members reviewed a draft minute from the May 2014 PTAC meeting and received a verbal update of the Gastrointestinal Subcommittee's views from PHARMAC staff.

1.5 The Subcommittee noted that the currently listed infliximab (Remicade, Janssen) is funded in DHB hospitals subject to restrictions for a range of inflammatory conditions including rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and plaque psoriasis refractory, or intolerant to the community TNF-alpha inhibitors adalimumab and/or etanercept, as well as various inflammatory bowel diseases (IBD), ocular inflammation and uveitis .

1.6 The Subcommittee noted that since the Hospital Medicines List (HML) came into effect the cost to DHBs of infliximab has increased significantly with growth mainly driven by increased use in IBD's. Members considered that improving the value for money on treatments was a reasonable goal for PHARMAC and DHBs.

1.7 The Subcommittee noted that Hospira's biosimilar infliximab (Inflectra/Remsima) had been approved by the European Medicines Agency (EMA) and had been launched in some European countries. Members noted that in order to satisfy the EMA for approval a biosimilar must demonstrate that its variability in any parameter falls within the range of variability for the reference product and that any differences between it and the reference product have no clinically meaningful differences in quality, safety or efficacy. Members noted that Medsafe was currently considering a submission for biosimilar infliximab but had yet to make a determination.

1.8 The Subcommittee reviewed evidence from two clinical studies comparing Hospira's biosimilar infliximab with Remicade: one Phase 1 pharmacokinetic study in patients with ankylosing spondylitis (Study CT-P13 1.1, PLANETAS, Park et al Ann Rheum Dis. 2013 ;72(10):1605-12) and one Phase 3 study in patients with rheumatoid arthritis (Study CT-P13 3.1, PLANETRA, Yoo et al Ann Rheum Dis. 2013;72(10):1613-20). The Subcommittee considered that it was not clear in the main publications if these studies enrolled biologic treatment naive patients.

1.9 The Subcommittee noted some differences in adverse events between the two treatment arms but considered that, overall, the evidence from these two studies indicated that Hospira's biosimilar infliximab had the same or similar safety and efficacy to Remicade.

1.10 The Subcommittee considered that it was reasonable to extrapolate the outcomes seen in rheumatoid arthritis and ankylosing spondylitis to other rheumatological settings.

1.11 The Subcommittee noted that no studies of Hospira's biosimilar infliximab had been undertaken in paediatric populations. Members noted that although Remicade was not indicated for paediatric rheumatological conditions, there was some published evidence for it in these settings. Members considered that Hospira's biosimilar infliximab should not be used in paediatric populations in the absence of pharmacokinetic evidence in a paediatric population.

1.12 The Subcommittee noted that switching from Remicade to Hospira's biosimilar infliximab had not been evaluated. Members noted that infliximab was immunogenic and considered that the risk of immunogenicity would be increased if patients switched back and forth between brands in an uncontrolled manner. The Subcommittee considered it would be safer if only one brand of infliximab were funded to avoid uncontrolled switching; therefore, members supported PHARMAC running a sole supply process for infliximab rather than having multiple brands funded.

1.13 The Subcommittee considered that a long sole supply period was preferable as this would limit the number of patients that would potentially be rechallenged with their earlier brand if awarding sole supply resulted in a brand switch. Members considered that whilst there was no local data to confirm this, they estimated that on average patients in NZ remained on infliximab for approximately 3 years.