Drug and Form	Listing Requested By Sponsor	Sponsor's Reasons For Seeking Review	Results Of Independent Review	PBAC Outcome and Comments	Sponsor comment
Naproxen with Esomeprazole, tablet, 500 mg – 20 mg (as magnesium trihydrate), Vimovo® AstraZeneca Pty Ltd TGA Indication: Vimovo is indicated for patients with an increased risk of gastrointestinal ulceration, who require NSAID therapy for symptomatic management of rheumatoid arthritis, ankylosing spondylitis and osteoarthritis with an inflammatory component AND in whom lower doses of naproxen or other NSAIDS have proven insufficient. If a daily dose of 1 g of	Listing requested: Restricted Benefit Symptomatic treatment of osteoarthritis, rheumatoid arthritis or ankylosing spondylitis in a patient who requires a non-steroidal anti-inflammatory (NSAID) and is at an increased risk of gastrointestinal ulceration in whom lower doses of naproxen or other NSAIDs are insufficient.	The issues upon which review is sought are: 1. PBAC criteria for fixed dose combination products 2. Validity of the surrogate outcome and non-inferiority 3. Continuing concern that the listing of Vimovo could result in increased costs to the PBS.	The Independent Review made 4 detailed recommendations and one overall recommendation: 1. That sufficient resources be devoted to the preparation of PBAC minutes to improve the detail, accuracy and clarity of the minutes. 2. That the PBAC amends Part IV of the Guidelines to make explicit any minimum requirements that must be met by Fixed Dose Combination products. 3. Considering surrogates Future submissions that involve drugs with surrogate outcomes should include a table that summarises information about the	The PBAC noted the findings of the Independent Review With regard to recommendation 1, the PBAC considered that the Review highlighted the need to ensure the clearest communication of its reasoning and decisions through the Committee Minutes and noted that the Department was evaluating the resources available for this task. With regard to recommendations 2, 3 and 4 the PBAC considered that matters related to the Guidelines referred to in the Independent Review should be addressed by the Guidelines Working	AstraZeneca looks forward to the publication of the full report in November 2013

naproxen is not required, Vimovo should not be used.			five Parts of the Surrogate to Final Outcomes Working Group (STFOWG) report. 4. Non-inferiority for drugs with multiple outcomes For drugs with multiple outcomes and for which economic analysis by cost-minimisation is being proposed, it would be helpful to have an explicit process of considering at least all the primary outcomes and deciding for which non-inferiority needs to be assessed. This is particularly important for combination drugs, especially when the two drugs are being used to affect different outcomes.	Group as a priority. Details of the Review's recommendations specific to Vimovo will be available with the publication of the Review and the related Public Summary Document. With regard to the overall	

			This process could be incorporated into PBAC Guidelines and the cost-minimisation checklist. Overall Recommendation That the matters raised in this Independent Review are best addressed in a major submission, informed by a pre-submission meeting.	recommendation, the PBAC confirmed its November 2012 rejection of the submission for the listing of Vimovo. The PBAC agreed with the Review's overall recommendation that the matters raised in the Independent Review are best addressed in a major submission, informed by a pre-submission meeting.	