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Correcting rheumatoid arthritis

Editor, – I wish to point out an error in ‘Disease modifying drugs in adult rheumatoid arthritis’ (*Aust Prescr* 2003;26:36–40). On page 38 the article says sulfasalazine contains acetylsalicylic acid and sulfapyridine. This should be 5-aminosalicylic acid and sulfapyridine.

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Your questions to the PBAC

Folinic acid, the PBAC and the TGA – approval confusion

Editor, – In December 2001 the Pharmaceutical Benefits Advisory Committee (PBAC) approved the listing of oxaliplatin as a pharmaceutical benefit. Oxaliplatin was listed as an authority item for use in metastatic colorectal cancer after failure of fluorouracil-based therapy in patients with a WHO performance status of two or less, to be used in combination with 5-fluorouracil and folinic acid.

Folinic acid is available in Australia in both oral and injectable forms. The indications approved by the Therapeutic Goods Administration (TGA) include megaloblastic anaemia due to folic acid deficiency and reducing the toxicity of folic acid antagonists.

The role of folinic acid in combination with 5-fluorouracil in colorectal disease is well documented. Its use in combination with oxaliplatin and 5-fluorouracil is also well documented. The folinic acid potentiates the antitumour activity of 5-fluorouracil by acting as a coenzyme.¹ However, the use of folinic acid for this indication has not been approved by the TGA.

How can oxaliplatin be approved by the PBAC for combination therapy with folinic acid in metastatic colorectal cancer when the folinic acid does not have an approved indication in this disease? On a separate note, why has the PBAC approved folinic acid in this combination, but not made it available as a pharmaceutical benefit?

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1. Dorr RT, Von Hoff DD, editors. *Cancer chemotherapy handbook*. 2nd ed. Norwalk, CT: Appleton & Lange; 1994.

PBAC response:

The PBAC thanks Mr Siderov for drawing this apparent anomaly to its attention. Drugs cannot be listed as pharmaceutical benefits unless the Therapeutic Goods Administration (TGA) has approved the indication. Oxaliplatin has TGA approval for use in the treatment of advanced colorectal cancer, in combination with 5-fluorouracil and folinic acid, and the Pharmaceutical Benefits Scheme (PBS) restriction is consistent with this indication.

Under the Therapeutic Goods Act, the TGA cannot compel a manufacturer to apply for a registered indication, nor can the TGA apply a registered indication to a drug if not requested by the manufacturer. In this case the registration of an indication for combination therapy would need to be sought by the manufacturers of folinic acid, rather than the manufacturers of oxaliplatin. Although use of folinic acid can only be promoted by its sponsor for its approved indications, a medical practitioner is not prevented under the Therapeutic Goods Act from using a product for an unapproved indication.

The PBAC noted that the injectable form of calcium folinate (3 mg/mL) was deleted from the PBS on 1 May 2002 at the request of the sponsor. The Department of Health and Ageing is seeking alternative sources of supply of the injection.