



MEDIA RELEASE

10 September 2003

## **API confident of meeting TGA compliance**

Group managing director of API, Mr David Young, is confident of rectifying all issues raised by the Therapeutic Goods Administration (TGA) regarding API's Kingsgrove manufacturing facility in approximately six weeks.

Mr Young said: "The TGA confirmed it had tested a sizeable sample of the company's goods and found no unsafe or incorrectly formulated products. All products are safe and consequently there is no need for a consumer recall of any of the company's products. TGA auditors are satisfied that the Company has consistently tested its products before putting them in the marketplace.

"The Company has taken the decision to voluntarily request suspension of our licence to manufacture therapeutic goods at our Kingsgrove facility in order to fix the issues raised by the TGA as quickly as possible and ensure that we comply with the highest Good Manufacturing Process (GMP) standards.

"We do not expect any significant disruption of supply to our customers due to the relatively short closure of the Kingsgrove manufacturing facility. We regret any inconvenience to our customers and expect to rectify the plant and process issues raised by the TGA."

Kingsgrove is one of API's three manufacturing sites and manufacturing is one of six businesses within API. The Kingsgrove operations contributed 3.8% of the API Group profit before tax and before significant one-off items to the Group's earnings for the 2002/3 financial year. The Kingsgrove operating expenses are approximately \$500,000 a month.

Mr Young emphasised four key points:

- the suspension of the Company's TGA licence resulted from a voluntary request by API;
- API's own testing and that of the TGA have confirmed that API's products are safe and there are no health issues;
- no consumer recall is required; and
- API is co-operating fully with the TGA.

For further information:

Mr David Young, Group Managing Director (Tel. 02 8844 2100)

Mr Peter Robinson, Chairman (Tel. 02 9232 7166)

Mr Chris Gardoll, Company Secretary (Tel. 02 8844 2101)