Peter M Brown

18th April, 2005.

Committee Secretary,
Community Affairs Committee,
Department of the Senate,
Parliament House,
CANBERRA ACT 2600.

Dear Sir/Madam,

RE: Inquiry into Services and Treatment Options for Persons with Cancer

I am a patient at St George Public Hospital. I am being treated by Prof. A Manoharan, Director of Clinical Haematology and the staff of St George Hospital Cancer Clinic.

I was diagnosed with Burkitts Non-Hodgkins Lymphoma of the spine with associated Leukaemia in June, 2004. My treatment with Chemotherapy is progressing through remission and into a current maintenance stage.

Amongst other drugs, this treatment has continued to include a monthly injection of Vincristine.

I am one of a percentage of Vincristine recipients who suffer a continuous deterioration of nervous system functions in both feet and hands.

This has been present now since June, 2004 and it is common for such situations to lead to permanent nervous system damage. To avoid this, the treatment is changed from Vincristine to Vindesine. This decision was made, but was then reversed when the hospital pharmacy brought to notice the supplier Aspen letter to them of 7th March 2005 advising withdrawal of Vindesine due to ongoing supply problems. (NB: Aspen has only recently taken over distribution of a number of drugs from its manufacturer, Eli Lilly Australia Pty Ltd. The original point of manufacture is not known to me).

I followed up this disturbing situation with Vanessa Thomas, employed by Aspen, who was most helpful. She was sent the attached advice dated 18th April, 2005 regarding how alternate supply opportunities may be sourced.

I have discussed this today with Prof. Manoharan, who has acknowledged this possibility but commented that generally speaking, it does not function satisfactorily because the medicines have to be available to suit the specific treatment schedule.

The problems experienced with the requirements in summary are:

- Time delay in identifying a reliable source of supply (Ms Thomas' phone advice recommended UK 'not on list' or Switzerland which had not yet responded to them)
- Time delay in processing such applications through the Australian system.
- Prof. Manoharan advised I was not the only patient affected and similar problems exist with other proven Chemotherapy drugs.

It is suggested that we need to find a simpler and more workable solution to this not uncommon problem in the interest of both the performance of the health system and its patients.

This problem is said not to be confined to St George Hospital. Prof. Manoharan and staff would be happy to co-operate with the Committee if required, to achieve a better understanding of this issue.

Yours faithfully,

Peter M Brown

ABN: 51 096 236 985
Suite 1, First Floor
34-36 Chandos Street, St Leonards NSW 2065
Phone: (61 2) 8436 8300 ~ Fax: (61 2) 9901 3540
Email: aspen@aspenpharmacare.com.au
Web: www.aspenpharma.com

Thurs 10/3/05

7 March 2005

The Manager
Pharmacy Department
St George Hospital
Gray St
Kogarah NSW 2217

Dear Sir

Eldisine (vindesine sulfate) and Oncovin (vincristine sulfate) to be discontinued

Aspen Pharmacare wishes to advise you that due to ongoing supply problems, the above products will be discontinued shortly. We anticipate that the current stock will run out by the end of May.
Therefore please make arrangements to employ alternative treatment options in place of Eldesine.

Yours sincerely,

Vanessa Thomas
Regulatory Affairs Manager

Greg Lee

Aspen Pharmacare Australia Pty Ltd
ABN: 51 096 236 985
Suite 1, First Floor
34-36 Chandos Street, St Leonards NSW 2065
Phone: (61 2) 8436 8300 ~ Fax: (61 2) 9901 3540
Email: aspen@aspenpharmacare.com.au
Web: www.aspenpharma.com.au

TO: Peter Brown

FROM: Vanessa Thomas

DATE: 18 April 2005

SUBJECT: **Eldesine (vindesine sulfate)**

Total number of pages dispatched including this page – 3

Dear Peter, as discussed, a search of Martindale has revealed that vindesine sulfate is available in the following countries:

- Belgium
- Finland
- France
- Germany
- Ireland
- Italy
- Netherlands
- Sweden
- Switzerland
- South Africa

One way of obtaining vindesine is to order it through an international pharmacy such as http://www.e-rx.net/products/antivert-market.html - this pharmacy lists vindesine as one of its products.
http://www.internationalpharmacies.com/
http://www.crossborderpharmacy.com/
http://www.pharmaworld.com/

To order vindesine, your doctor has to apply to the Therapeutic Goods Administration (TGA) for permission to bring the product into the Australia. This is done under the Special Access Scheme (SAS), Category B.
Please find attached information on the SAS.

Please note that until we run out of stock of vindesine, it will be listed on the TGA's register of therapeutic goods. Therefore your doctor will need to explain to the medical officer at the TGA that Aspen intends discontinuing the product and hence his application to import it into the country on your behalf.

Yours sincerely

Vanessa Thomas
Regulatory Affairs Manager

TGA THERAPEUTIC GOODS ADMINISTRATION
PO Box 100 Woden ACT 2606 Australia
Telephone: (02) 6232 8444 Facsimile: (02) 6232 8241
ABN 40 939 406 804

Health and Aged Care

FREQUENTLY ASKED QUESTIONS - THE SAS

- **What therapeutic goods are available through SAS?**

With the exception of drugs of abuse where the manufacture, possession, sale or use is prohibited by State or Territory law, all unapproved therapeutic goods can potentially be supplied via the SAS.

- **How long does it take to process an application?**

Category A — is a notification only. TGA does not send out a letter of acknowledgment. The medical practitioner completes the Category A "Authority to Supply " form and sends it to the sponsor of the product and a copy to the TGA. This provides the sponsor with the legal authority to supply the product.

Category B — generally, for commonly requested products TGA has a turnaround time of 2 working days from time of receipt of the application until a response is prepared and mailed. Applications for products not previously requested under the SAS may take longer.

- **What if my request is urgent?**

Under this circumstance, a phone request can be made. Alternatively, the application can be faxed to the TGA. On the bottom of your application please write: 'FAX RESPONSE ASAP'.

NOTE: phone requests should be reserved for cases where there is an urgent medical need for access to the product.

- **I wish to bring a product into Australia for commercial supply. Can I do this under the SAS?**

No. The SAS is a mechanism by which individual named patients can access an unapproved therapeutic good through their medical practitioner. Therapeutic goods intended for commercial supply in Australia are required to undergo an evaluation for quality safety and efficacy prior to being allowed on the market. The various mechanisms for supply of unapproved products are intended to be **temporary** measures for supply, pending general marketing approval of the product. Unfettered access to unapproved products amounts to de-facto marketing and would remove any incentive for a sponsor to seek marketing approval for their products.

In keeping with its overall charter, the TGA has a responsibility to encourage at all times the availability of approved (evaluated) products.

- **My doctor does not know anything about this product. Can I write my own SAS application?**

No. A doctor must write an SAS application and must be able to justify on medical grounds why his/her patient requires the unapproved product.

The treating doctor is best placed to determine the needs of the patient, including whether or not treatment with a particular unapproved product is required. It is expected that, in accordance with good medical practice, a medical practitioner will educate him/herself with all relevant and available information about an unapproved product before using it.

It is also important to note that a medical practitioner has the right to decline to prescribe an unapproved product if he/she believes there is either insufficient clinical justification or no evidence to support the use of the product.

- **How do I get the product once the TGA has given approval?**

If the product is available from a supplier in Australia, you should contact the supplier (sponsor) to organise supply. Within an institution supply of a medicine can usually be arranged by the pharmacy department. The supplier will require authorisation to release the product. In the case of supply for a category A patient, the completed 'Authority to Supply' form acts as the authorisation. For category B patients, an approval number is issued by the TGA and will appear in an approval letter sent to the requesting doctor by the TGA. This number must be quoted in all correspondence with the sponsor.

If the product is not available from an Australian sponsor, the requesting doctor will need to find an overseas source. The product will then need to be imported from that supplier. This can be done by the doctor, a pharmacist, hospital, by the patient or by a licensed importer. When seeking to arrange importation of an unapproved medicine, it is important to check whether it is controlled under Customs (Prohibited Import) Regulations, in which case it cannot be imported without an import permit. A full list of controlled substances is available on the TGA Website: http://www.health.gov.au/tga/docs/html/bringmed/intoaust.htm. When approval is given under the SAS for supply of a controlled medicine, TGA will automatically issue an import permit.

- **Does TGA approval (or notification of Category A use) automatically mean I can access the product?**

No. Sponsors are under no obligation to supply an unapproved product merely because the TGA has given an approval. Before submitting an application to the TGA, doctors should check with the sponsor to see if they are prepared to supply the product. In addition, TGA approval does not override any State/Territory requirements that need to be met before the product can be supplied lawfully. These requirements can be product specific and applicants need to check these with their State/Territory health department. Contact details can be found in local telephone books.