

Product information required by the TGA

Sponsors have been asked to complete this Product Questionnaire for each and every product on the Australian Register of Therapeutic Goods (ARTG) where they are the nominated sponsor and Pan Pharmaceuticals is a nominated manufacturer.

1. Please post out (see address below) the completed forms for each and every product on the Australian Register of Therapeutic Goods (ARTG), where you are the nominated sponsor and Pan Pharmaceuticals Limited is a nominated manufacturer to the TGA by close of business on Wednesday 30th April.

AND

2. Either email (preferably) to tga.sime@health.gov.au or fax (see fax numbers below) to the TGA, **by close of business on Wednesday 30th April**, the completed forms for those products that have been manufactured by Pan Pharmaceuticals Limited from 1st May 2002.

Please fax to one of the following fax numbers:

Sponsor name starts with the letter	Please use these fax numbers	
A-G	(02) 62328577	(02) 62328913
H-O	(02) 62328659	(02) 62328399
P-Z	(02) 62328299	(02) 62328643

TGA postal address:

Director
 Non Prescription Medicines Branch
 Therapeutic Goods Administration
 PO Box 100
 Woden
 ACT 2606

Checklist to ensure compliance:

Action required	Action complete
I have completed the Product Questionnaire for all products which I am the nominated sponsor and Pan Pharmaceuticals Limited is a nominated manufacturer.	
I have emailed or faxed, by close of business on Wednesday 30th April , the completed forms for those products that have been manufactured by Pan Pharmaceuticals Limited from 1 st May 2002*.	
I have posted out the completed forms for each and every product on the Australian Register of Therapeutic Goods (ARTG), where I am the nominated sponsor and Pan Pharmaceuticals Limited is a nominated manufacturer to the TGA by close of business on Wednesday 30 th April.	
I have ceased supply of all batches of product that have been manufactured by Pan Pharmaceuticals Limited from 1 st May 2002.	
I have instigated voluntary recall procedures for batches of product that have been manufactured by Pan Pharmaceuticals Limited from 1 st May 2002 and supplied in Australia.	

***NB: The TGA will be phoning you, if you have more than 100 products where Pan Pharmaceuticals Limited is a nominated manufacturer, to assist you with providing the TGA with the necessary information.**

Further information can be found on the TGA website (www.TGA.health.gov.au) or by phoning the TGA on (02) 62328805.

Product Information required:

1. Sponsor name: Sponsor Enterprise I.D. Number:
2. ARTG product name:
3. ARTG number:
4. Have you nominated Pan Pharmaceuticals Limited as the sole principle manufacturer for this product?
 Yes No
5. Has this product been manufactured by Pan Pharmaceuticals Limited since 1st May 2002:

Yes No —————> I confirm that the product shown above has not been manufactured by Pan Pharmaceuticals Limited since 1st May 2002:



.....
(Signature of Company Secretary)

.....
(Date)

If yes, please provide the following information:

6. Steps of manufacture carried out by Pan Pharmaceuticals:
(a) Manufacture of dosage form. (d) Testing (Chemical and physical testing).
(b) Testing (Microbial testing). (e) Packaging and labelling.
(c) Release for supply. (f) Do not know.
7. For each batch manufactured since 1st May 2002 please provide the following information:
(a) Batch Number (b) Date of manufacture (c) Expiry date (d) Export Only (Y/N)

➤ For product supplied in Australia only, please indicate whether you will be instigating a voluntary recall for those above batches of product supplied in Australia: Yes No

8. Has any batch of this product been manufactured since 1st May 2002 been exported?

Yes No

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If yes, please provide the following details:

- Name of importing countries:
- Name and contact details of importer/supplier/customs forwarding or clearing agent in each country:
- Name of product (if known) in the importing countries:
- Any other information that may assist with the identification of the product in the importing country:

I confirm that the information supplied above is true and correct.

.....
(Signature of Company Secretary)

.....
(Date)