Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

TGA Contact Officer: Josh Wiley
Telephone number: (02) 6232 8943

The Managing Director
Radpharm Scientific a Division of Global Medical Solutions Australia Pty Limited
PO Box 3334
Bmdc
BELCONNEN ACT 2617

Attention: Barbara Rooks

Dear Madam

New Condition(s) of Listing under Section 28 of the *Therapeutic Goods Act 1989*

AUST L 157322 - Nexavir

As Delegate of the Secretary, for the purposes of Paragraph 28(3) of the *Therapeutic Goods Act 1989*, I am imposing the following condition on the listing of the above medicine for export only:

- *The sponsor shall hold stability data to support the claimed shelf life of the listed medicine according to the labelled storage conditions. The sponsor will provide stability data to the Director, Office of Non Prescription Medicines, Therapeutic Goods Administration upon request, except where the overseas importer accepts responsibility for stability studies. When an overseas importer accepts responsibility for providing stability data for this product, it is the sponsor's responsibility to ensure that they have a written agreement to this effect from the overseas importer. The sponsor will provide a copy of this agreement to the Director, Office of Non Prescription Medicines, Therapeutic Goods Administration upon request.*

- *It is a condition of listing that medicines which have been included in the Australian Register of Therapeutic Goods as 'export-only goods' under Section 26 or Section 26A of the Therapeutic Goods Act, 1989, must not be supplied for sale in Australia, including supply via duty free outlets.*

This additional condition takes effect 28 days after the date of this notice.

Appeal under Section 60 of the *Therapeutic Goods Act 1989*

This Decision is an "initial decision" within the meaning of section 60 of the *Therapeutic Goods Act 1989*. This means that if your interests are affected by the decision, you may seek reconsideration by the Minister. Any appeal should be made in writing within 90 days after this decision first comes to your notice or to the notice of your company, and should be sent to the following address:

The Parliamentary Secretary to the Minister
for Health and Ageing
Parliament House
CANBERRA ACT 2600

This letter should be headed "APPEAL UNDER SECTION 60 OF THE THERAPEUTIC GOODS ACT 1989".

The Parliamentary Secretary may either deal with the appeal personally or send it to be dealt with by one of the Minister's delegates within the Department. Should you be dissatisfied with the result of your appeal then, subject to the *Administrative Appeals Tribunal Act 1975*, you may appeal to the Administrative Appeals Tribunal for review of the Minister's/Delegate's decision.

Yours faithfully

Mohammed Ali
Delegate of the Secretary
1/12/2008

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

ARTG Certificate

Issued to

Radpharm Scientific a Division of Global Medical Solutions Australia Pty Limited

for approval to supply

Nexavir

ARTG Identifier **AUST L 157322**
ARTG Start date **28/11/2008**

Product type: **Listed (Export Only) Medicine**

Manufacturer(s) Details	Address	Manufacturing steps
AMS Laboratories Pty Limited	8 Rachael Close SILVERWATER, NSW, 2128	Testing microbial
Radpharm Scientific a Division of Global Medical Solutions Australia Pty Limited	54-59 Oatley Court BELCONNEN, ACT, 2617	Packaging and labelling Release for supply Manufacture of dosage form Secondary packaging Sterilisation Testing chemical and physical

ARTG Standard Conditions

The above Medicine Listed (Export Only) has been entered on the Register subject to the following conditions:

- Except where the sponsor has been contracted by an overseas party to manufacture the goods and that party will be responsible for placing the goods on the market in countries other than Australia, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods and, upon the request of the Director, Office of Non Prescription Medicines, Therapeutic Goods Administration, shall produce such evidence to the Director.
- The conditions applying to these goods when they are exported from Australia are given below:
- Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995, other than condition No. 8 and condition No. 9.
- Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995, other than condition No.11
- The sponsor shall hold stability data to support the claimed shelf life of the listed medicine according to the labelled storage conditions. The sponsor will provide stability data to the Director, Office of Non Prescription Medicines,TGA upon request, except where the overseas importer accepts responsibility for stability studies. When an overseas importer accepts responsibility for providing stability data for this product, it is the sponsor's responsibility to ensure that they have a written agreement to this effect from the overseas importer. The sponsor will provide a copy of this agreement to the Director, Office of Non Prescription Medicines, TGA upon request.
- It is a condition of listing that medicines which have been included in the Australian Register of Therapeutic Goods as 'export-only goods' under Section 26 or Section 26A of the Therapeutic Goods Act, 1989, must not be supplied for sale in Australia, including supply via duty free outlets.

Products covered by this Entry

1. Nexavir

Product Specific Conditions

No specific conditions have been recorded against this entry.

Product Standard Indications

No standard indications have been recorded against this entry.

Product Specific Indications

- Nexavir is used in the treatment of dermatological conditions where inflammation and edema are apparent

Warnings

No warnings have been recorded against this entry.

Dosage Form

Injection, solution

Route of Administration

Intramuscular

Visual Identification

Clear Brown Solution

Product Formulation(s)

Active Ingredients

	Quantity	Units
Liver extract	25.5	mg/mL

END OF CERTIFICATE

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