



# health

Department:  
Health  
REPUBLIC OF SOUTH AFRICA

## MEDICINES CONTROL COUNCIL

The Registrar of Medicines, Private Bag X828, PRETORIA, 0001

Tel:

Fax:

Enquiries:

Reference:

### FAX AND MAIL TO

Ms K Jamaloodien

National Dept of Health  
Private Bag x 828  
Pretoria

0001

Fax: 0865818823

MR MOHLAMME MOKONE

CYTARINE  
02/45/2016

Datum \* Date

01 November 2016

Tel: 0123959167

Fax: 0862743073

Dear Ms Jamaloodien,

### **REQUEST TO USE UNREGISTERED MEDICINE IN TERMS OF SECTION 21 OF THE MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 1965 (ACT 101 OF 1965):**

Your application dated 21 Oct 2016 refers

- |                                   |   |
|-----------------------------------|---|
| <b>A. STATUS:</b>                 | Approved.                               |
| <b>B. APPLICANT:</b>              | Ms K Jamaloodien                        |
| <b>C. IMPORTING COMPANY:</b>      | Equity Pharmaceuticals (pty) Ltd        |
| <b>D. PATIENT/(S):</b>            | Emergency stock                         |
| <b>E. UNREGISTERED MEDICINES:</b> |   |
| <b>GENERIC NAME:</b>              | Cytarabine                              |
| <b>TRADE NAME:</b>                | CYTARINE                                |
| <b>QUANTITY:</b>                  | Cytarabine (100 mg) vial x 10 455 vials |
| <b>F. APPROVAL NUMBER:</b>        | N2/19/9/1 (CYTARINE) 02/45/2016         |

Please include this letter with any future correspondence to our offices to facilitate efficient processing of your documentation

### **PROGRESS REPORTS**

Both the supplier and the Medicines Control Council should receive a full Progress Report at the time of termination of treatment (18 April 2017). In the case of long term treatment a follow-up report must be submitted every six months. A new authorisation number must be obtained every six months

Yours faithfully,

Dr S Munbodh

for and on behalf of REGISTRAR OF MEDICINES

MCC SECTION 21 REFERENCE NO: S161021/33