GOVERNMENT GAZETTE

OF THE

REPUBLIC OF NAMIBIA

N$2.00 WINDHOEK - 10 November 2006 No. 3735

CONTENTS

Government Notice

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 193 2006

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 1965
REGISTRATION OF CERTAIN MEDICINES

In terms of section 17 of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), the registrar gives notice that the medicines set out in the Schedule have been registered in terms of that Act.

The conditions subject to which the medicines are registered are stipulated under the note to that Schedule.

Note:

The above medicines are registered subject to the following conditions:

(a) the manufacture of medicine and the control of medicine must be done in accordance with current good manufacturing practices as required by the World Health Organisation;

(b) in order to assess compliance with paragraph (a), investigations and inspections may be carried out by inspectors, authorized in terms of section 26 of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), at such reasonable times as the council may consider necessary;

(c) every manufacturer of medicine must, with the approval of the council, ensure that the information contained in the medicine package insert is regularly updated and varied so as to provide accurate information to the user of the medicine;

(d) the provisions of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), apply to every manufacturer of medicine registered in terms of section 15 of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965);

(e) the quality, safety and therapeutic efficacy of the registered medicine will be reviewed on a regular basis, and if necessary the registration of such medicine varied;

(f) the first two production batches must be fully validated in terms of the detailed process validation protocol submitted at the time of application for registration;

(g) a validation report must be submitted within one month from the date of completion of the validation process referred to in paragraph (f); and

(h) the council may review the registration dossier at such intervals as may be determined by the council.

_____