GOVERNMENT GAZETTE

OF THE

REPUBLIC OF NAMIBIA

N$5.00 WINDHOEK - 20 September 2006 No. 3704

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Government Notice

MINISTRY OF HEALTH AND SOCIAL SERVICES

No. 159 2006

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

In terms of section 17 of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965) ("the Act"), I give notice that the medicines set out in the Schedule have been registered in terms of the Act, subject to the following conditions:

(a) The manufacture and control of the medicines must be in accordance with the existing Good Manufacturing Practices as required by the World Health Organisation;

(b) in order to assess compliance with paragraph (a), inspections and investigations may be carried out regularly by inspectors authorised in terms of section 26 of the Act;

(c) the information in the package insert must regularly be updated to conform to the package insert approved by the council;

(d) the holder of the certificate of registration, referred to in section 15(4) of the Act, must comply with the Act;

(e) the registration of medicine is subject to regular review regarding its quality, safety and efficacy, and the council may when necessary vary the registration of the medicine;

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

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

(h) the council may review the registration dossier and may determine the intervals when such review will take place.

J ≠GAESEB
REGISTRAR OF MEDICINES