GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. R. 308 **22 April 2013**

MEDICINES AND RELATED SUBSTANCES ACT, (ACT NO. 101 OF 1965)

GENERAL REGULATIONS: DRAFT AMENDMENT

The Minister of Health intends, in terms of section 35 of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) and after consultation with the Medicines Control Council, to make the regulations in the Schedule.

Interested persons are invited to submit any substantiated comments or representations on the proposed amendment regulations to the Director-General: Health, Private Bag X 828, Pretoria, 0001 (for the attention of the Director: Affordable Medicine) within three months of the date of the publication of this notice.

SCHEDULE

Definitions

1. In these regulations **"the Regulations"** means the General Regulations as published under Government Notice No. R510 of 10 April 2003, as amended.

Amendment of regulation 20 of the Regulations

2. Regulation 20 of the Regulations is hereby substituted with the following Regulation:

"20 Period of validity of a license issued in terms of regulations 18 and 19 and renewal of licenses

(1) A license issued in terms of regulation 18 shall, provided that the holder pays the applicable annual fee, remain valid until it is suspended or revoked by the Director-General in terms of section 22E of the Act.

(2) A license issued in terms of regulation 19 shall be valid for a period of 5 years from the date of issue.

(3) A license referred to in subregulation (2) which has expired may be renewed upon application to the Council.

(4) An application referred to in subregulation (3) shall –
(a) contain at least the information or documentation referred to in regulation 19(1)(c);
(b) be accompanied by a prescribed fee; and
(c) be made at least 90 days before expiry of the existing license.".

DR A MOTSOALEDI, MP
MINISTER OF HEALTH
DATE: 13/9/2013

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