DEPARTMENT OF HEALTH

No. R. 929 **30 September 2005**

AMENDMENTS TO THE SUPPLEMENTARY REGULATIONS MADE UNDER THE INTERNATIONAL HEALTH REGULATIONS ACT, 1974 (ACT NO. 28 OF 1974)

The Minister of Health intends, in terms of section 3(2) of the International Health Regulations Act, 1974 (Act No. 28 of 1974), to make the supplementary regulations in the Schedule.

Interested persons are invited to submit any substantiated comments or representations on the proposed regulations to the Director-General of Health, Private Bag X828, Pretoria, 0001 (for the attention of the Directorate: Pharmaceutical Programmes and Planning), within three months of the date of publication of this notice.

SCHEDULE

1. In these supplementary regulations, **"the Regulations"** means the supplementary regulations published under Government Notice No. R. 2001 of 24 October 1975, as amended by Government Notices Nos. R. 2069 of 20 October 1978 and R. 790 of 18 April 1980.

Amendment of regulation 1 of the Regulations

2. Regulation 1 of the Regulations is hereby amended by the insertion of the following definitions in the correct alphabetical order:

"applicant" means a medical practitioner, nurse or pharmacist working at a health establishment who applies for a licence in terms of these regulations;

"Department" means the national Department of Health;

"Director-General" means the head of the national Department of Health;

"international certificate of vaccination" means the form printed by the Government Printers and distributed by a vaccine supplier and provided to a licence holder for issuing to a patient who is vaccinated against yellow fever by a licence holder at a vaccinating

centre;

"health district", in relation to a district municipality or a metropolitan municipality, means an area which is under the jurisdiction of such municipality;

"health establishment" means any public or private facility, including a vehicle or mode of transport providing any health services;

"licence" means a licence issued by the Director-General in terms of these regulations to an applicant for the purpose of administering yellow fever vaccine at a specific vaccinating centre;

"licence holder" means an applicant to whom the Director-General issued a licence in terms of these regulations for the purpose of administering yellow fever vaccine at a vaccinating centre;

"manager of a vaccinating centre" means a person responsible for the services rendered by such vaccinating centre;

"medical practitioner" means a person registered as such under the Health Professions Act, 1974 (Act No. 56 of 1974);

"nurse" means a person registered as such under the Nursing Act, 1978 (Act No. 50 of 1978);

"patient" means a person who requests to be vaccinated against yellow fever;

"pharmacist" means a person registered as such under the Pharmacy Act, 1974 (Act No. 53 of 1974;

"special event" means a national or international event involving large numbers of heads of state;

"vaccinating centre" means a health establishment designated by the Minister by notice in the *Gazette* which is situated at a specific physical address where yellow fever vaccination is administered by a licence holder;

"vaccine supplier" means any pharmaceutical agent for vaccine distribution licensed by

the Medicines Control Council of South Africa to sell vaccines registered in terms of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965);

"yellow fever service" means the administering of a yellow fever vaccine if, according to the licence holder, such administration is safe, informing the patient of possible side effects and contra-indications of yellow fever vaccination and provision of information on the prevention of yellow fever;

"yellow fever vaccine" means a vaccine against yellow fever supplied by a producer approved by the World Health Organization and which is registered as such in terms of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965);

Addition of Chapter V to the Regulations

3. The supplementary regulations are hereby amended by the addition of the following Chapter after Chapter IV:

"CHAPTER V
YELLOW FEVER

Administering of yellow fever vaccine

35. No person shall administer a yellow fever vaccine unless he or she is a licence holder.

36. No person shall receive a yellow fever vaccination unless such vaccination is administered by a licence holder within a vaccinating centre.

Application for a licence and designation of vaccinating centre

37. (1) An applicant desiring to obtain a licence shall apply in writing to the Director-General.

(2) An application referred to in subregulation (1) shall be accompanied by a non-refundable application fee of R450 which shall be used by the Department for the purposes of administering the licensing of vaccinating centres.

(3) The application fee referred to in subregulation (2) shall be paid into the relevant bank account of the Department to be specified by the Director-General.

(4) The application shall contain at least the following information:

(a) The full names, residential and business addresses (both physical and postal) of the applicant;

(b) the exact location and name of the health establishment where yellow fever vaccinations will be carried out;

(c) proof that a postgraduate course in travel medicine and tropical diseases or any other similar course approved by a statutory council, has been successfully completed by the applicant;

(d) telephone number(s), cellular phone number(s) and fax number(s) of the applicant;

(e) proof by applicant of current registration with the relevant statutory council;

(f) motivation for the need for a licence in a particular area; and

(g) any other information that the Director-General may require.

(5) The Director-General shall review the application and forward such application to the relevant provincial Department of Health for comment.

(6) The provincial Department of Health referred to in subregulation (5) shall review the application and report back in writing to the Director-General with regard to the following:

(a) The existence of other vaccinating centres in the health district concerned; and

(b) the geographic area in the health district concerned to be served by the applicant.

(7) The Director-General shall cause the health establishment concerned to be inspected with regard to -

(a) *management of yellow fever vaccine;*

(b) staff;

(c) refrigeration and temperature monitoring;

(d) recording systems; and

(e) good pharmacy practice.

(8) On the basis of the written report from the relevant provincial Department of Health referred to in subregulation (6) and on the basis of the inspection referred to in subregulation (7), the Director-General shall decide whether or not to issue a licence.

(9) If the Director-General decides to issue a licence, the Director-General shall inform the applicant in writing thereof and request such applicant to pay a non-refundable annual licence fee of R100 into the bank account of the Department referred to in subregulation (3).

(10) The applicant shall submit proof of payment after which the Director-General shall issue a licence.

(11) If the Director-General decides not to issue a licence, the Director-General shall inform the applicant in writing thereof, providing the reason(s) for not issuing a licence.

(12) On the basis of the issuing of a licence referred to in subregulation (10), the Minister shall, by notice in the *Gazette,* designate the health establishment where the licence holder shall administer yellow fever vaccine unless such health establishment has already been designated.

Limitation of vaccinating licences and vaccinating centres in a health district

38. (1) The Director-General shall issue only one licence to each applicant and such licence shall be valid for a specific designated vaccinating centre only.

(2) A licence shall be valid for a period of three years and such licence is not transferable to any other person.

(3) The Director-General may limit the number of licences to be issued in a health district according to the needs of the population in such district.

(4) The Minister may limit the number of designated vaccinating centres according to the needs of the population in the health district concerned.

(5) The needs of the population referred to in subregulations (3) and (4) shall be determined by Director-General on the basis of, *inter alia*, the annual reports referred to in regulation 43 and the register kept by the Director-General.

Withdrawal of a licence

39. The Director-General may withdraw a licence if the licence holder concerned -

(1) does not comply with these regulations;

(2) is deregistered with the statutory council concerned; or

(3) is not resident in the Republic of South Africa.

Withdrawal of designation of a vaccinating centre

40. The Minister may by notice in the *Gazette* withdraw the designation of a vaccinating centre if -

(1) there is no licence holder employed at such vaccinating centre; or

(2) the vaccinating centre ceases to exist.

Renewal of a licence

41. (1) A licence holder may apply to the Director-General in writing for the renewal of a licence.

(2) The procedure referred to in regulation 36 for the issuing of a licence shall also be applicable for the renewal of a licence.

Responsibilities

42. (1) The manager of a vaccinating centre shall –

(a) keep the register in which a licence holder(s) employed at such centre shall indicate the following information:

(i) The number of yellow fever vaccines administered per month by each licence holder;

(ii) the age, gender and town or city of origin (home address) of each patient vaccinated against yellow fever;

(iii) the number of patients who were refused yellow fever vaccination;

(iv) the destination of patient and reason why patient requested yellow fever vaccination; and

(v) any adverse reactions to the yellow fever vaccine;

(b) ensure that a licence holder is present or on call at the vaccinating centre at all times; and

(c) submit an annual report on or before 15 January of each year to the relevant provincial Department of Health and to the Director-General indicating the information referred to in paragraph (a).

(2) A licence holder shall -

(a) provide a yellow fever service only at the vaccinating centre indicated on

the licence: Provided that such yellow fever service shall be in line with the requirements as determined in section 22A of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965);

(b) provide a yellow fever service to any person on request;

(c) follow any guidelines for the prevention and treatment of specific travel-related diseases, travel-related conditions and health hazards (including vaccination techniques, storage of vaccines and reporting of adverse events) as recommended by the Department;

(d) administer, prescribe and supply only vaccines and medicines registered in terms of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965);

(e) have a system in place to keep abreast of relevant travel medicine information and outbreaks of diseases worldwide;

(f) accumulate not less than 50% of the Continuing Professional Development points required by the Health Professions Council of South Africa in travel medicine or related fields which shall be compulsory for the renewal of a licence;

(g) have access to an electronic network system (email) to ensure rapid communication when outbreaks of diseases occur or when reviewing of travel medicine information is necessary;

(h) complete, sign and issue an international certificate of vaccination;

(i) use an official stamp in the format determined in Annexure attached *hereto on an international certificate of vaccination; and*

(j) issue a duplicate of an international certificate of vaccination to a patient only if the original international certificate of vaccination issued to such patient has been lost and relevant records of the patient are still available at the vaccinating centre.

General

43. (1) Every provincial Department of Health shall, on the basis of the annual reports submitted by vaccinating centres in that province, establish and maintain a register regarding yellow fever vaccinations in such province indicating at least the following information:

(a) The number of yellow fever vaccines administered per month per vaccinating centre;

(b) the age, gender and town or city of origin (home address) of each patient vaccinated against yellow fever;

(c) the number of patients who were refused yellow fever vaccination;

(d) the destination of patient and reason why patient requested yellow fever vaccination;

(e) the number of vaccinating centres in each health district in such province; and

(f) the total population in each health district in such province.

(2) The Department shall, on the basis of the annual reports submitted by vaccinating centres, establish and maintain a register regarding yellow fever vaccinations indicating at least the following information:

(a) The number of yellow fever vaccines administered per month per vaccinating centre;

(b) the age, gender and town or city of origin (home address) of each patient vaccinated against yellow fever;

(c) the number of patients who were refused yellow fever vaccination;

(d) the destination of patient and reason why patient requested yellow fever vaccination;

(e) the number of vaccinating centres in each health district per province;

(f) the total population in each health district per province;

(g) date when a licence was issued, licence number concerned and name of vaccinating centre where the licence holder is working; and

(h) date of payment of licence fee by a licence holder.

(3) The Department shall establish and maintain a register of fees obtained in terms of these regulations, which shall indicate at least the following information.

(a) Details of applicant;

(b) Date of payment of the application fee;

(c) date of issue of licence ;

(d) the licence number;

(e) date of payment of the licence fee;

(f) the date of licence renewal; and

(g) date of payment of the renewal fee.

(5) Notwithstanding any provisions in these regulations, the Director-General may issue a temporary licence to a person to administer yellow fever vaccine in the following circumstances:

(a) Special event; or

(b) yellow fever outbreak.

(6) A temporary licence referred to in subregulation (5) shall indicate the period for which such licence shall be valid.

Transitional arrangements

45. (1) A medical practitioner, nurse or pharmacist who was granted temporary approval by the Director-General before the promulgation of these regulations for functioning as vaccinating centres shall within a period of six months after the promulgation of these regulations, apply for a licence.

(2) Temporary approval referred to in subregulation (1) as well as approval for a licence referred to in subregulation (1) shall expire 12 months after the promulgation of these regulations.

(3) A medical practitioner, nurse or pharmacist referred to in subregulation (1) who does not apply within the period of six months referred to in subregulation (1) and who applies for a licence, shall be subject to the procedure stipulated in regulation 37.

Dr ME Tshabalala-Msimang, MP
Minister of Health
14. 7. 2005

Annexure

EXAMPLE OF FORMAT OF OFFICIAL STAMP ON AN INTERNATIONAL CERTIFICATE OF VACCINATION

"Dr A N Y Other MB ChB
Execujet Lanseria Airport Travel Clinic
Auth. No. GP 42/02 TC
for Department of Health"

or, if not functioning under a specific name

"Dr A N Y Other MB ChB
Auth. No. GP 34/02 TC
For Department of Health"

Note: (1) the above-mentioned letters must be small enough to fit into block on international certificate of vaccination

(2) Line 1: Indicate initials, surname and qualification(s) of licenced medical practitioner, nurse or pharmacist and who is responsible for the functioning of the vaccinating centre concerned

(3) Line 2: If the vaccinating centre concerned is functioning under a specific name, e.g. Pretoria Travel Clinic, this name should be included, otherwise, if the vaccinating centre is part of a general practice, leave out

(4) Line 3: Specific authorisation Number of vaccinating centre concerned allocated by the Department

(5) Line 4: Add the phrase "for the Department of Health"