

No. R. 185

9 MARCH 2007

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

The Minister of Health has, in terms of section 3(2) of the international Health Regulations Act, 1974 (Act No. 28 of 1974), made the regulations in the Schedule.

SCHEDULE

1. In these regulations, **“the Regulations”** means the supplementary regulations published under Government Notice No. R. 2001 of 24 October 1975, as amended by Government Notices No’s. 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:

“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;

“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;

“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 a person 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 number 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, or a mobile centre, where yellow fever vaccine 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 the 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 yellow fever vaccine unless he or she is a **licence holder**.

Application for a licence and designation of vaccinating centre

36. (1) An applicant for a licence shall apply in writing to the Director-General.
- (2) An application referred to in sub-regulation (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 centre's.
- (3) The application fee referred to in sub-regulation (2) shall be paid into the relevant bank account of the Department, as specified by the Director-General by notice in the *Gazette*.
- (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 vaccinating centre where yellow fever vaccinations will be carried out;
 - (c) Proof that a course in travel medicine and tropical diseases or any other similar course approved by a health 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 health statutory council; and
 - (f) Any other information that the Director-General may require.
- (5) 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.
- (6) 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 sub-regulation (3).

- (7) The applicant shall submit proof of payment after which the Director-General shall issue a licence.
- (8) 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.
- (9) On the basis of the issuing of a licence referred to in sub-regulation (7), 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 licences

37. (1) The Director-General shall issue only one licence to each applicant and the holder of such licence shall be entitled to use it in any designated vaccinating centre.
- (2) A licence shall be valid for a period of five years and such licence is not transferable to any other person.

Withdrawal of a licence

38. The Director-General may withdraw a licence if the licence holder concerned –
 - (1) Does not comply with these regulations;
 - (2) Is deregistered from the statutory council concerned; or
 - (3) Is not resident in the Republic of South Africa.

Withdrawal of designation of a vaccinating centre

39. 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

40. (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

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

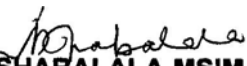
- (a) Keep the register in which a licence holder(s) employed at such centre shall indicate the following information:
 - (i) The number of yellow fever vaccines administered per month by each licence holder;
 - (ii) The town or city of origin (home address) of each patient vaccinated against yellow fever;
 - (iii) The number of patients who refused yellow fever vaccination and reasons for such refusal;
 - (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 Director-General indicating the information referred to in paragraph (a).
- (2) A licence holder shall –
- (a) provide a yellow fever service only at a designated vaccinating centre: Provided that such yellow fever service shall be rendered in accordance with the requirements as determined in section 22A the Medicines and Related Substances Act, 1965 (Act No.101 of 1965);
 - (b) 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;
 - (c) Have a system in place to keep abreast of relevant travel medicine information and outbreaks of diseases worldwide;
 - (d) Have a system in place to ensure rapid communication when outbreaks of diseases occur or when reviewing of travel medicine information is necessary;
 - (e) Complete, sign and issue an international certificate of vaccination;
 - (f) Use an official stamp, in the format determined in Annexure A attached hereto, on an international certificate of vaccination; and

- (g) 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 the relevant records of the patient are still available at the relevant vaccinating centre.

General

42. (1) 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 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.
- (2) 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) Licence number;
 - (e) Date of payment of the licence fee;
 - (f) Date of licence renewal; and
 - (g) Date of payment of the renewal fee.

- (3) 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.
- (4) A temporary licence referred to in sub-regulation (5) shall indicate the period for which such licence shall be valid.


ME TSHABALALA-MSIMANG
MINISTER OF HEALTH
02-02-2007

ANNEXURE

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

Example 1 (for medical practitioner)

“Dr A N Y Other MBChB
Execujet Lanseria Airport Travel Clinic*
Auth. No. GP 42/02 TC
For Department of Health”

* Leave out if the name of travel clinic or other specific name if the vaccination centre is not functioning under that name but forms part of a general practice

Example 2 (for nurse or pharmacist)

“A N Y Other
Execujet Lanseria Airport Travel Clinic
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 (of both the examples): Indicates initials, surname and qualification(s) of licensed medical practitioner, nurse or pharmacist who is responsible for the functioning of the vaccinating centre concerned.
 - (3) Line 2 (of example 1): The specific name of the vaccinating centre.
 - (4) Line 3 (of both examples): Specific authorization number of vaccinating centre concerned allocated by the Department
 - (5) Line4 (of both examples): Add the phrase “for the Department of Health”