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The Gazette of the Democratic Socialist Republic of Sri Lanka

EXTRAORDINARY

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No. 2149/25 – THURSDAY, NOVEMBER 14, 2019

(Published by Authority)

PART I: SECTION (I) – GENERAL

Government Notifications

L.D.B. 7/2009

NATIONAL MEDICINES REGULATORY AUTHORITY ACT, NO. 5 OF 2015

REGULATIONS made by the Minister of Health, Nutrition and Indigenous Medicine under Paragraph (bb) of Subsection (2) of section 142 of the National Medicines Regulatory Authority Act, No. 5 of 2015 read with paragraphs (n) and (o) of section 14 and subsection (2) of section 137 of the Act.

DR. RAJITHA SENARATNE,(M.P.)
Minister of Health, Nutrition and Indigenous Medicine.

Colombo,
05th November, 2019

Regulations

1. These regulations may be cited as the Regulations for the issue of Lot Release Certificate for Vacancies and Sera No. 1 of 2019.

2. (1) A person shall not sell, offer for sale, display, promote, Market or distribute within Sri Lanka any Vaccines or Sera, except under the authority of a Lot Release Certificate (hereinafter referred to as the ''Lot Release Certificate'').

   (2) A Lot Release Certificate issued by the National Control Laboratory of the Medical Research Institute of Sri Lanka (hereinafter referred to as the ''NCL'') shall be required for all Government procured and private sector procured vaccines and sera including donations.

3. An application for a Lot Release Certificate shall be substantially in the form specified in Shedule 1 and shall be made either by-

(i) the Director Medical Supplies Division of the Ministry of Health in case of Public sector procurements;

(ii) the Chief Epidemiologist for the National Immunization Programme Vaccines; or

(iii) the holder of the Certificate of Registration under section 62 of the Act in case of private sector procured vaccine,

hereinafter referred to as the ''Applicant''

4. Even though a Certificate of Registration has been issued for a vaccine or a serum under section 62 of the Act, the holder of a Certificate of Registration shall obtain a Lot Release Certificate to undertake any activity specified in regulation 2.

5. (1) The Lot Release Certificate shall be issued by the NCL for each lot of vaccine or serum:-

(a) on the availability of the Lot Release Certificate issued by the National Control Laboratory or the National Regulatory Authority of the manufacturing country with protocol review as a minimun criterion; and

(b) having assessed and the critical review of the summary protocol.

(2) In case a new vaccine is introduced to Sri Lanka, vaccine testing shall be performed in addition to the protocol review. The first three lots of vaccines shall be tested for this purpose and where necessary a random test may also be undertaken.

Provided however, vaccines pre-qualified by the World Health Organization may be exempted from such requirement.

6. In addition to the summary protocol review, certain vaccines and sera may require laboratory testing by the NCL. The needed samples shall be supplied by the applicant as may be required.

7. The NCL shall require the applicant to provide five single dose vials or three multi dose vials from each lot of vaccine or such other quantities as may be otherwise required, as control samples for each vaccine. These samples shall be obtained from each lot of vaccine in respect of which the Lot Release Certificate is issued.

8. Where laboratory testing is not required the Lot Release Certificate shall be issued by the NCL within two weeks of receipt of samples and certified copies of all necessary documents specified in the guidelines set out in Scheduld II.

9. The fee payable in respect of processing an application for a Lot Release Certificate and quality testing shall be as specified in Schedule III. Such fees shall not be applicable to vaccines and sera procured by the Government and donations. The fees shall be reviewed at least every two years.

10. (1) Where the NCL is satisfied that the applicant has fulfilled the required criteria, the NCL shall issue the Lot Release Certificate substantially in the form specified in the Schedule IV.

(2) Where the applicant has not fulfilled the required criteria or if the NCL is not assured of the quality, the NCL shall reject the application and shall notify the applicant and the National Medicines Regulatory Authority in writing with reasons for such rejection.

11. Where Sri Lanka does not have expertise or facilities to perform a quality testing, the required samples shall be sent to a reference laboratory recognised by the World Health Organization to obtain the Quality Test Report. The cost for transport, processing fee and the fees for testing at reference laboratory shall be borne by the manufacturer of the vaccine or serum or the local agent of such manufacturer.

12. (1) Where any issues relating to unsatisfactory clinical responses, adverse reactions and exposure to bad storage conditions having being observed by any person, the NCL shall be notified initially by telephone within twenty four hours of becoming aware of such issues. Samples of such vaccines or sera shall be sent for quality testing when requested by the NCL together with an application substantially in the form specified in Schedule V.

(2) The required number of samples may vary and be communicated with the NCL and the quality testing fees shall be as specified in the Schedule III.

13. The Lot Release Certificate shall be valid only in respect of the particular lot of vaccine mentioned in the Lot Release Certificate. If there are more than one lot in one consignment separate Lot Release Certificates shall be obtained for each lot.

14. (1) The Fast Track Lot Release may be considered in situations of national disasters or emergencies and where a vaccine or serum is out of stock. The minimum documentation required for approval of a Fast Track Lot Release shall be as follows:

(i) The Certificate of Pharmaceutical Product which includes Good Manufacturing Practice Certificate and free sales certificate;

(ii) The Lot Release Certificate issued by the National Control Laboratory or the National Regulatory Authority of the country of Manufacture;

(iii) Certificate of Analysis issued by the National Control Laboratory or the National Regulatory Authority of the country of manufacture.

(2) If the NCL is satisfied with the minimum documentation, the product may be released for emergency use without a Lot Release Certificate, subject to conditions specified in writing;

Provided however, the summary protocols shall be submitted to the NCL within one month

(3) Where discrepancies relating vaccines and sera released for use are identified during protocol review, such vaccine or serum shall be withdrawn or withheld from usage.

(4) Where a vaccine or serum is withdrawn or withheld from usage the manufacturer or his agent shall be accordingly informed in writing. The appropriate measures for re-export or destruction shall be carried out as soon as possible, on such terms and conditions as may be most appropriate. All expenses shall be borne by the manufacture or his agent.

15. In these regulations:

''Act'' means National Medicines Regulatory Authority Act, No.5 of 2015.

''Lot release'' means the process of review, evaluation, and quality control carried out on an individual lot of a registered vaccine or serum, before giving approval for its release to the market;

''National Immunization programme'' means the organizational component of the Ministry of Health charged with preventing diseases, disability and death from vaccine preventable diseases in the country;

''Quality Test Report'' means the report issued by any National Control Laboratory or a reference laboratory after performing the necessary laboratory testing according to World Health Organization or accepted pharmacopeial standards on the submitted sample of the particular batch of vaccines or sera;

''reference laboratory'' means, a laboratory implementing international best practices for laboratory operations recognized by World Health Organization and which receives specimens from other referring laboratories for testing,

''Summary Protocol'' means, a document based on the World Health Organization model Summary protocol containing detailed information on all manufacturing steps, quality control of seed lots, each single harvest, final bulk, finished product and test results for a lot of vaccines or sera, which is certified and signed by the responsible person of the manufacturer.

SCHEDULE I [Regulation 3]

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வைத்திய ஆராய்ச்சி நிலையம்
MEDICAL RESEARCH INSTITUTE
NATIONAL CONTROL LABORATORY
SRI LANKA

M R I

Application Form for Lot Release Certificate for Vaccines and Sera

Office use only:

Ref No:	

1. Applicant's information		
1.1 Name		
1.2 Address		
1.3 Contact person in Sri Lanka		
1.4 Contact details	Phone:	email:
2. Vaccine/ Serum information		
2.1 Name of the vaccine/serum		
2.2 Trade name		
2.3 Name of manufacturer		
2.4 Address of Manufacturer		
2.5 Marketing Authorization Registration No:	2.6 Lot No:	
2.7 Date of manufacture:	2.8 Expiry date:	
2.9 Storage condition:	2.10 Type of container: ☐ Vial ☐ Ampoule ☐ Prefilled syringe	
2.11 Number of doses per container:		
2.12 Quantity of vaccine imported:	2.13 No. of vials sent to National Control Laboratory:	
3. Diluent information (if any)		
3.1 Name of diluent:	3.2 Manufacture same/different. If so name and address of the manufacturer:	
3.3 Lot No:		
3.4 Manufacturing date:	3.5 Expiry date:	
3.6 Storage condition:	3.7 Type of container: ☐ Vial ☐ Ampoule ☐ Prefilled syringe	

4. Documentation

4.1 Documents submitted:

- ☐ Summary lot protocols
- ☐ Package insert leaflet
- ☐ Certificate of analysis of diluent
- ☐ Airway bill and importing packing list
- ☐ Lot release certificate from National Regulatory Authority / National Control Laboratory
- ☐ Certificate of analysis of finished product
- ☐ Temperature monitoring data during transportation
- ☐ Registration certificate issued by National Medicines Regulatory Authority

5. Applicant's declaration

I hereby certify that the above information is true and correct to the best of my knowledge. I understand that if any of the above information is found to be false or untrue or misleading or mispresented I may be held liable for it and this application will be rejected. Any payments made will not be refunded.

Name and Designation	Signature	Date

Phone: 0112693532-4, 0112698660 Fax: 0112691495 P.O. Box 527, Dr. Danister De Silva Mw. Colombo 08

Web: www.mri.health.gov.lk

[Regulation 8]

SCHEDULE II

Guidelines for the Submission of Documents and Samples

All the documents shall be written in English. The following documents and samples are to be submitted in the manner specified:

(1) An application form shall be signed by the applicant requesting for a lot release. An application form may be obtained from the official websites of the National Medicines Regulatory Authority and Medical Research Institute.

(2) Summary lot protocol of the vaccine or serum.
The protocol submitted by the manufacturer should reflect all appropriate production and control steps for a particular product as outlined in the marketing authorisation dossier for that specific product. Results of the tests are required (passed or failed is not sufficient, initial results and, where applicable, results of retests should be given). Specifications for each test and dates when the tests were performed and completed should also be included.

(3) Lot Release Certificate issued by the National Control Laboratory or the National Regulatory Authority of the manufacturing Country.

(4) Package information leaflet.

(5) Certificate of analysis of the finished product by the manufacturer.

(6) Certificate of analysis of any applicable diluents by the manufacturer.

(7) Importing packing list.

(8) Airway bill.

(9) Marketing authorization registration certificate issued by the National Medicines Regulatory Authority.

(10) Temperature monitoring data during transporation.

As temperature deviation could happen during transportation or redressing, applicant must submit relevant date and supporting documents such as thermal cycling studies and shipping validation to justify temperature excursion for each product. The data must be sufficient to prove that the vaccine products remain stable at those storage conditions.

(11) Any other document that may be required by the National Control Laboratory.

(12) Required number of vaccine or serum vials as samples.

(13) In - house reference standards (working reference standards), where necessary.

(14) Applicable fees.

[Regulation 9]

SCHEDULE III

Fees payable in respect of processing an application for a Lot Release Certificate and Quality Testing

Every application shall be submitted upon payment of the processing fee and the fee necessary for the relevant test when indicated.

The fees shall be as follows:

(1) Processing fee for a Lot Release application - Rs. 20,000
(2) Quality testing fees:

(a) Sterility test - Rs. 10,000
(b) Innocuity (abnormal toxicity) test - Rs. 10,000
(c) Potency testing

(i) Measles vaccine - Rs. 20,000
(ii) Oral poliomyelitis vaccine - Rs. 20,000
(iii) Rabies vaccine - Rs. 50,000
(iv) Anti-rabies serum - Rs. 15,000

If the application has been submitted, the fees referred to above shall not be refunded.

SCHEDULE IV [Regulation 10]

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MEDICAL RESEARCH INSTITUTE
NATIONAL CONTROL LABORATORY
SRI LANKA

M R I

National Control Laboratory – Lot Release Certificate

Examined under the Gazette notification No.1052/3 of 02/11/1998 and according to the section 137 (2) of National Medicines Regulatory Authority Act No. 5 of 2015.

Name of the vaccine/serum	
Trade name	
Name and address of manufacturer	
Name and address of sample sender	
Sample sender's reference and date	
Type of container	
Number of doses per container	
Prescribed storage temperature	

Lot No.	Manufactured Date	Expiry Date	No. of containers released

This vaccine / serum lot is in compliance with the specifications approved in the marketing authorization and all national and relevant World Health Organization requirements*, and the lot is released.

This examination is based on
- ❑ the review of the manufacturing and testing protocols
- ❑ the appropriate control laboratory tests as indicated in the vaccine testing policy

Certificate No:	Date of issue:

Signature:

Name and designation of authorized signatory: ....., Head / National Control Laboratory
As is applicable

*WHO good manufacturing practices for pharmaceutical products;
*WHO good practices for biological products;
*WHO guidelines for independent lot release of vaccines by regulatory authorities;
*WHO guidelines or recommendations for relevant vaccine or serum.

Copy to – Chairman, National Medicines Regulatory Authority

Phone: 0112693532-4, 0112698660 Fax: 0112691495 P.O. Box 527, Dr. Danister De Silva Mw. Colombo 08

Web: www.mri.health.gov.lk

SCHEDULE V [Regulation 121]

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MEDICAL RESEARCH INSTITUTE
NATIONAL CONTROL LABORATORY
SRI LANKA

M R I

Application Form for Quality Testing of Vaccines and Sera

Office use only:

Ref No:	

1. Applicant information	
1.1 Name and address of applicant	
1.2 Contact person	
1.3 Contact number	
2. Vaccine/Serum information	
2.1 Name of the vaccine or serum	
2.2 Trade name	
2.3 Name and address of manufacturer	
2.4 Marketing Authorization Registration No:	2.5 Lot No:
2.6 Date of manufacture:	2.7 Expiry date:
2.8 Storage cordition at the institute:	2.9 Type of container: ☐ Vial ☐ Ampoule ☐ Prefilled syringe
2.10 Number of doses per container:	
2.11 Dosage and route of administration:	2.12 No. of vials sent to National Control Laboratory:
2.13 Stock available at institute from same batch:	
3. Diluent information (if any)	
3.1 Name of diluent:	3.2 Manufacture same/different. If so name and address of the manufacturer:
3.3 Lot No:	
3.4 Manufacturing date:	3.5 Expiry date:
3.6 Storage condition:	3.7 Type of container: ☐ Vial ☐ Ampoule ☐ Prefilled syringe
4. Nature of the problem /complaint with all relevant details:	
5. Documentation	
5.1 Documents submitted: ☐ Lot release certificate issued from National Control Laboratory ☐ Cold chain maintenance records ☐ Registration certificate issued by National Medicines Regulatory Authority ☐ Fully completed form of report of adverse reactions to vaccines/ sera	
6. Applicant's declaration	
I hereby certify that the above information is true and correct to the best of my knowledge. I understand that if any of the above information is found to be false or untrue or misleading or mispresented I may be held liable for it and this application will be rejected. Any payments made will not be refunded.	

Name and Designation	Signature	Date

Phone: 0112693532-4, 0112698660 Fax: 0112691495 P.O. Box 527, Dr. Danister De Silva Mw. Colombo 8
Web: www.mri.health.gov.lk