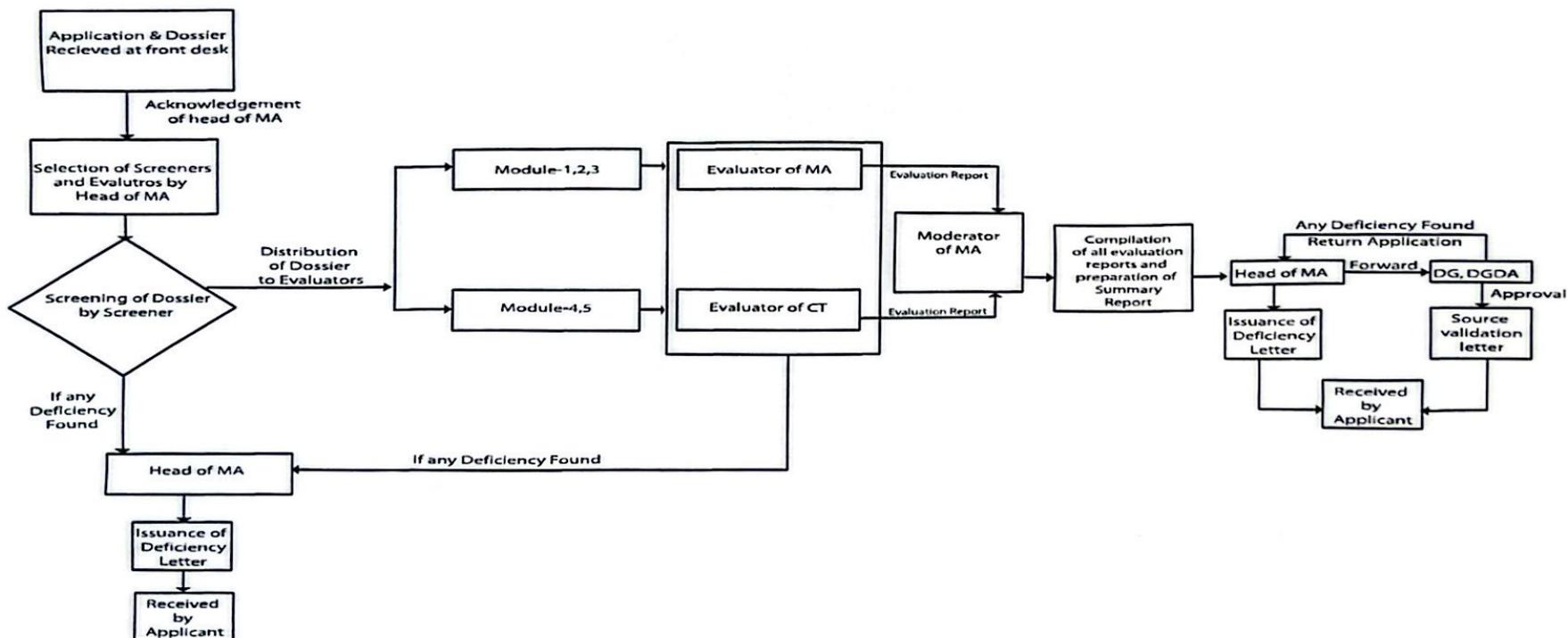


**DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH**

Authorized Personnel Only

| Annexure – 1 | | | | | | |
|---|---|----------------|-------------|---|----------|---|
|  | FORM Title: Flowchart for the registration procedure for introduced vaccine and biological products manufactured in Bangladesh (Locally manufactured product by using imported bulk) | | | | |  |
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Source Validation of Vaccine and Biological Products



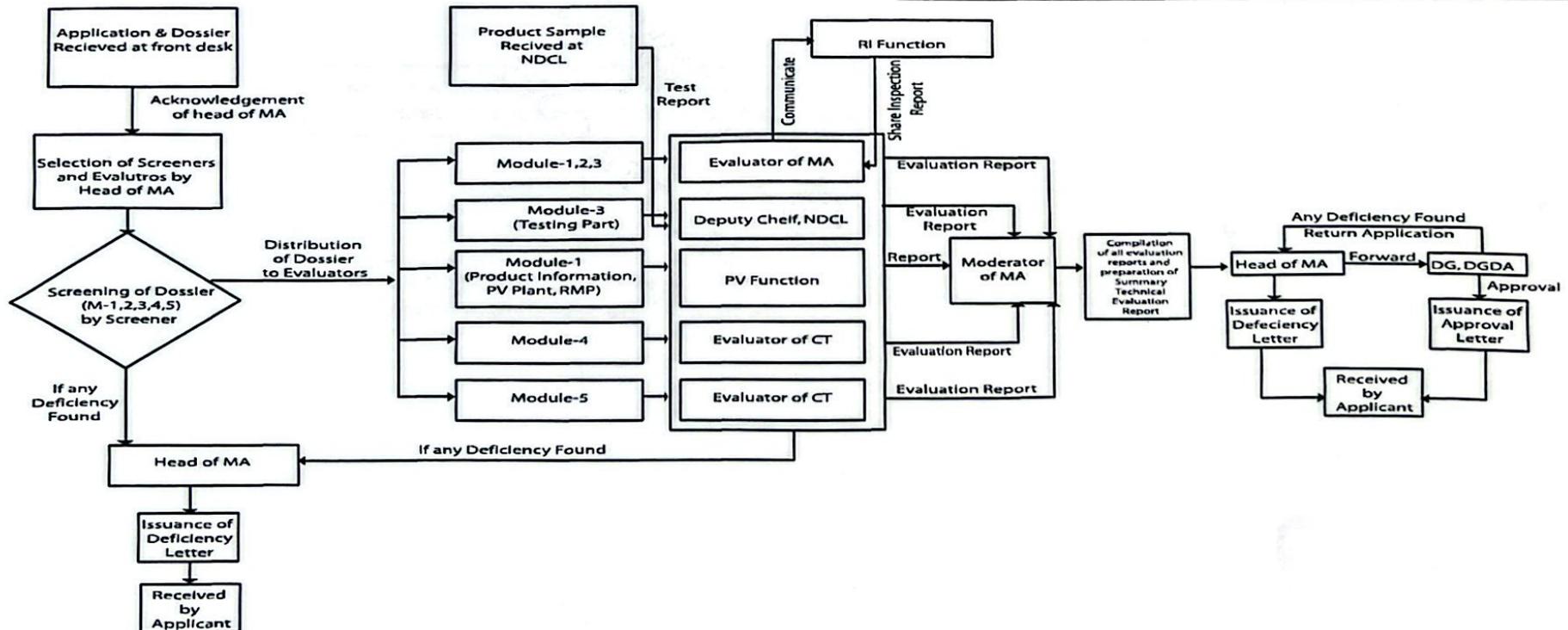
DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

Authorized Personnel Only

Annexure – 1

| | | | | | | |
|---|---|----------------|-------------|---|----------|---|
|  | FORM Title: Flowchart for the registration procedure for introduced vaccine and biological products manufactured in Bangladesh (Locally manufactured product by using imported bulk) | | | | |  |
| Form No. | Version No. | Effective Date | Review Date | Approved by | Date | Page No. |
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Registration Procedure for Introduced Vaccine and Biological Products



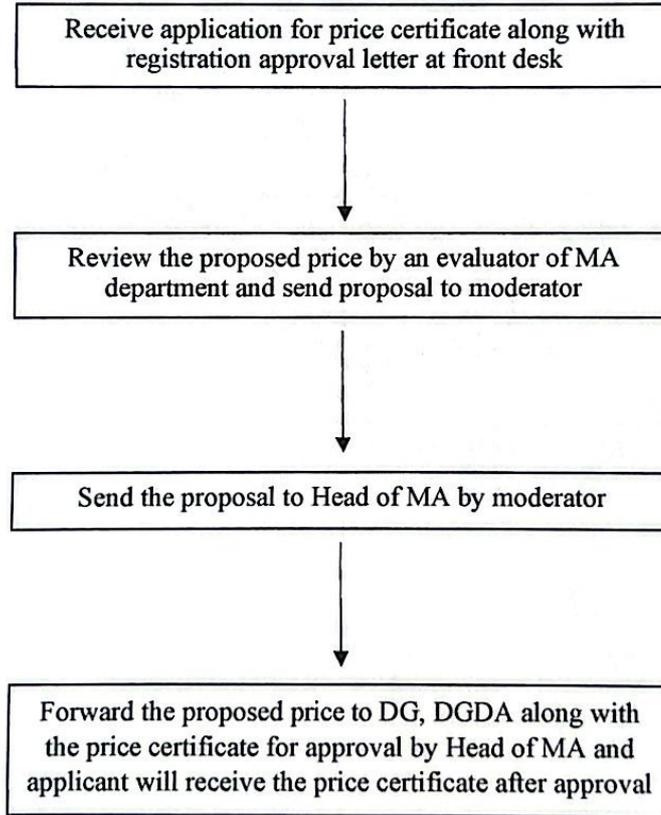
DIRECTORATE GENERAL OF DRUG ADMINISTRATION

MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

Authorized Personnel Only

| Annexure-1 | | | | | | |
|---|---|----------------|-------------|--|----------|---|
|  | FORM Title: Flowchart for the registration procedure for introduced vaccine and biological products manufactured in Bangladesh (Locally manufactured product by using imported bulk) | | | | |  |
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Price certificate issuance



Tentative time needed to execute price certificate issuance is 07 days. Calculation of tentative time depends on as per submission of applicant's consecutive deficient documents.

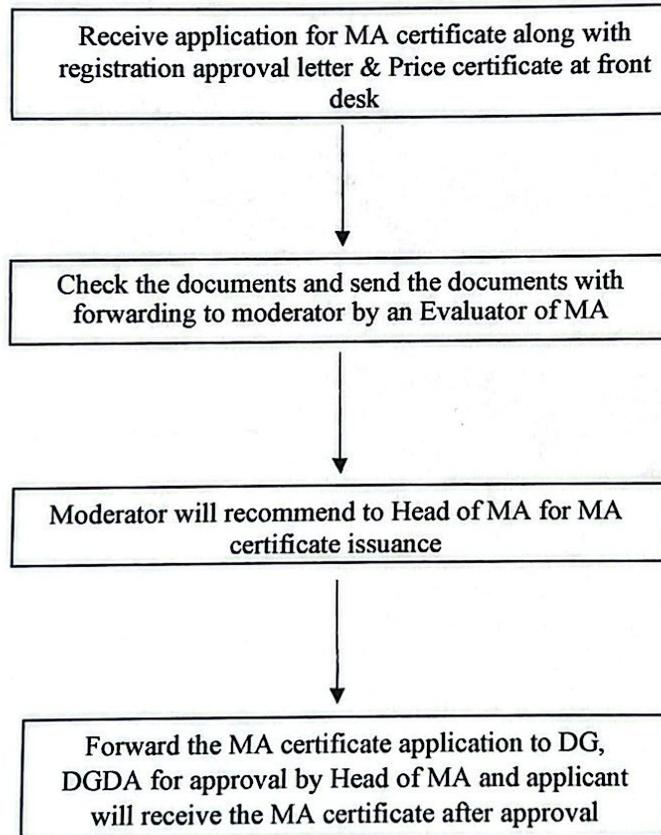
DIRECTORATE GENERAL OF DRUG ADMINISTRATION

MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

Authorized Personnel Only

| Annexure-1 | | | | | | |
|---|---|----------------|-------------|--|----------|---|
|  | FORM Title: Flowchart for the registration procedure for introduced vaccine and biological products manufactured in Bangladesh (Locally manufactured product by using imported bulk) | | | | |  |
| Form No. | Version No. | Effective Date | Review Date | Approved by | Date | Page No. |
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MA certificate



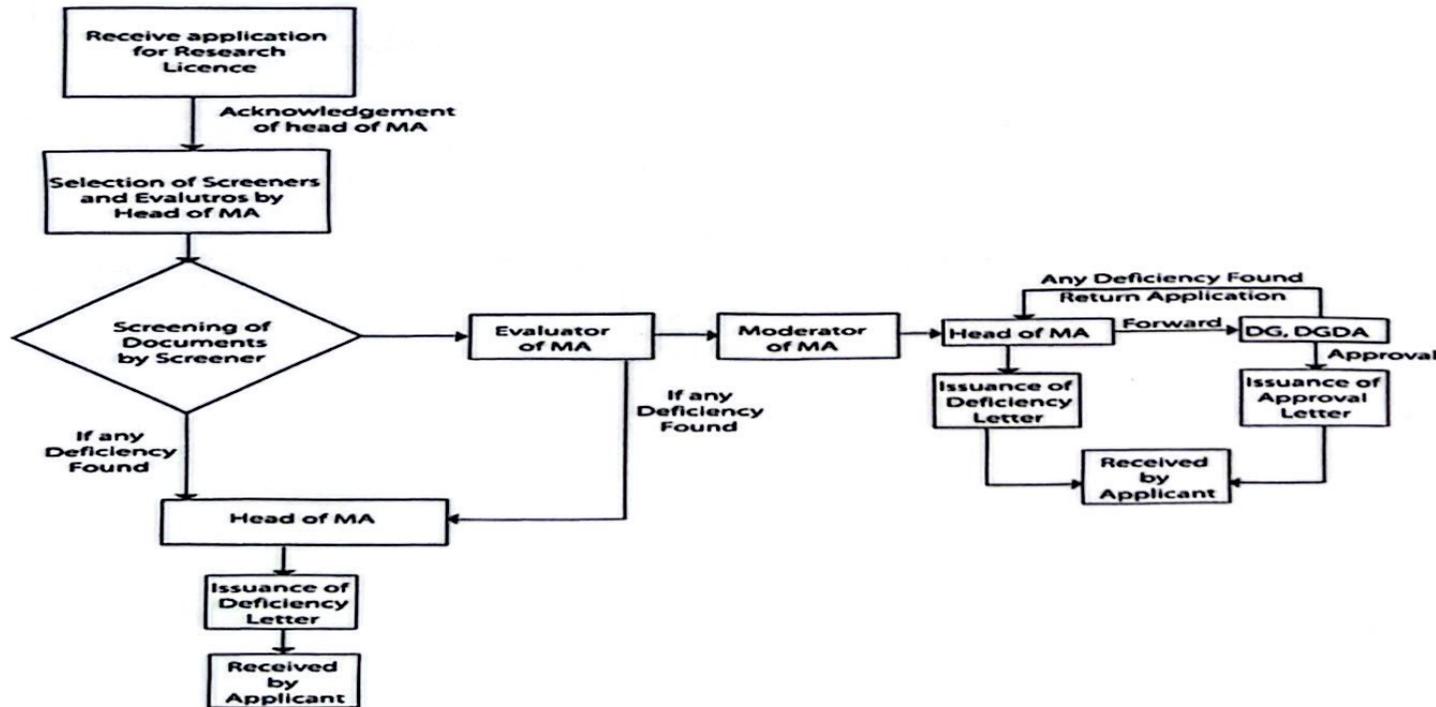
Tentative time needed to execute MA certificate issuance is 15 days. Calculation of tentative time depends on as per submission of applicant's consecutive deficient documents.

DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

Authorized Personnel Only

| Annexure – 2 | | | | | | |
|---|--|----------------|-------------|---|----------|---|
|  | FORM Title: Flowchart for the registration procedure for introduced vaccine and biological products manufactured in Bangladesh (Locally Developed Vaccine & Biological Bulk Antigen or Product) | | | | |  |
| Form No. | Version No. | Effective Date | Review Date | Approved by | Date | Page No. |
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Application for Research License



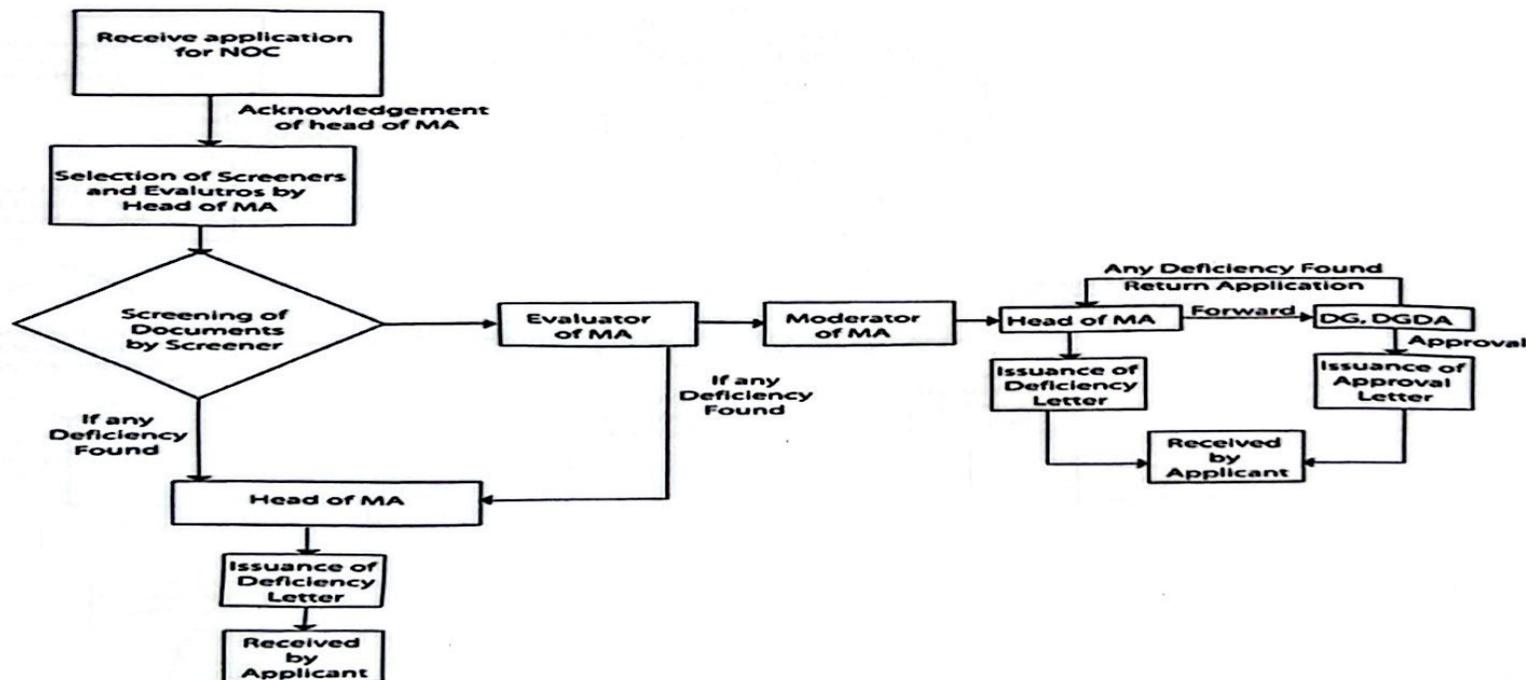
DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

Authorized Personnel Only

Annexure – 2

| | | | | | | |
|---|--|----------------|-------------|---|----------|---|
|  | FORM Title: Flowchart for the registration procedure for introduced vaccine and biological products manufactured in Bangladesh (Locally Developed Vaccine & Biological Bulk Antigen or Product) | | | | |  |
| Form No. | Version No. | Effective Date | Review Date | Approved by | Date | Page No. |
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Issuance of NOC for Importation of any substances and cells

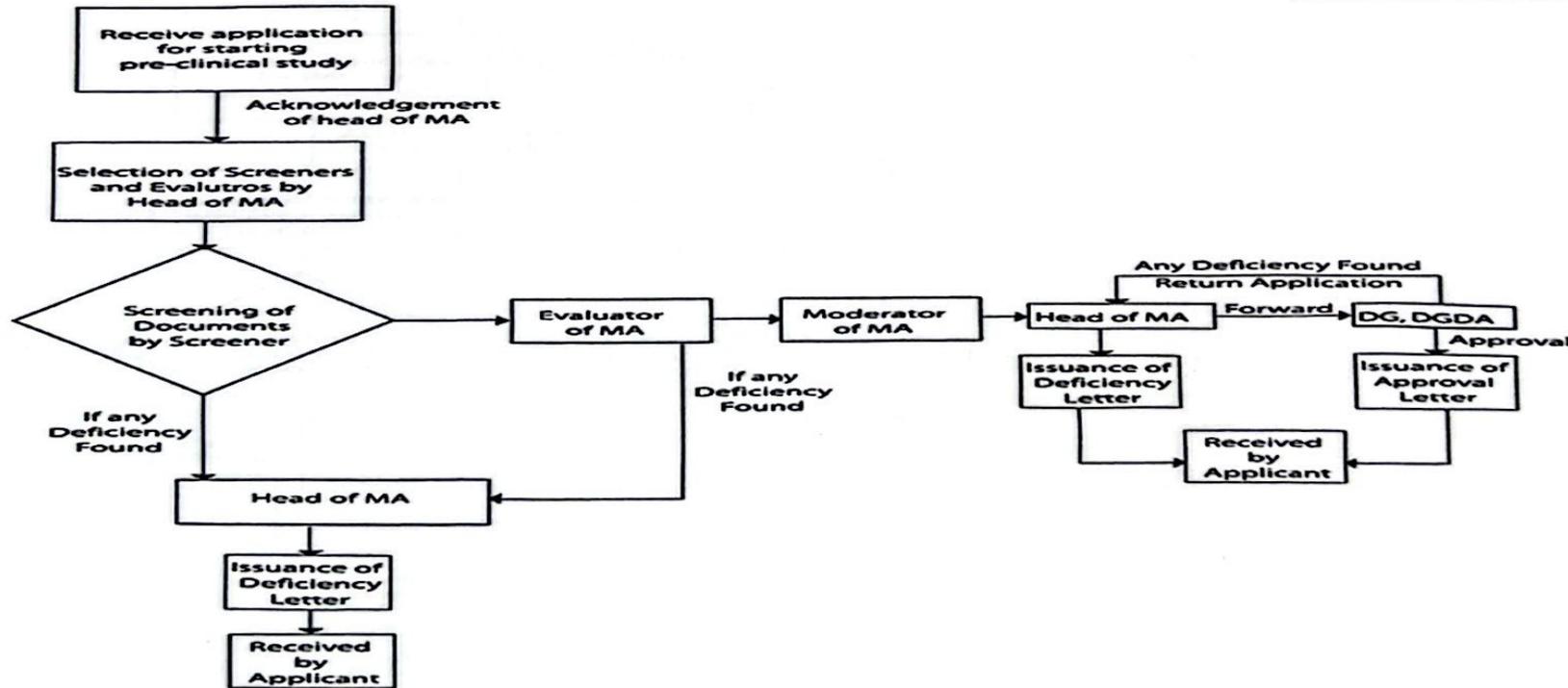


DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

Authorized Personnel Only

| Annexure – 2 | | | | | | |
|---|--|----------------|-------------|---|----------|---|
|  | FORM Title: Flowchart for the registration procedure for introduced vaccine and biological products manufactured in Bangladesh (Locally Developed Vaccine & Biological Bulk Antigen or Product) | | | | |  |
| Form No. | Version No. | Effective Date | Review Date | Approved by | Date | Page No. |
| NRA-MA-013/F02-02 | 06 | JAN' 25 | JAN' 29 |  | 10.12.24 | 03 of 07 |

Approval to Perform Preclinical Study

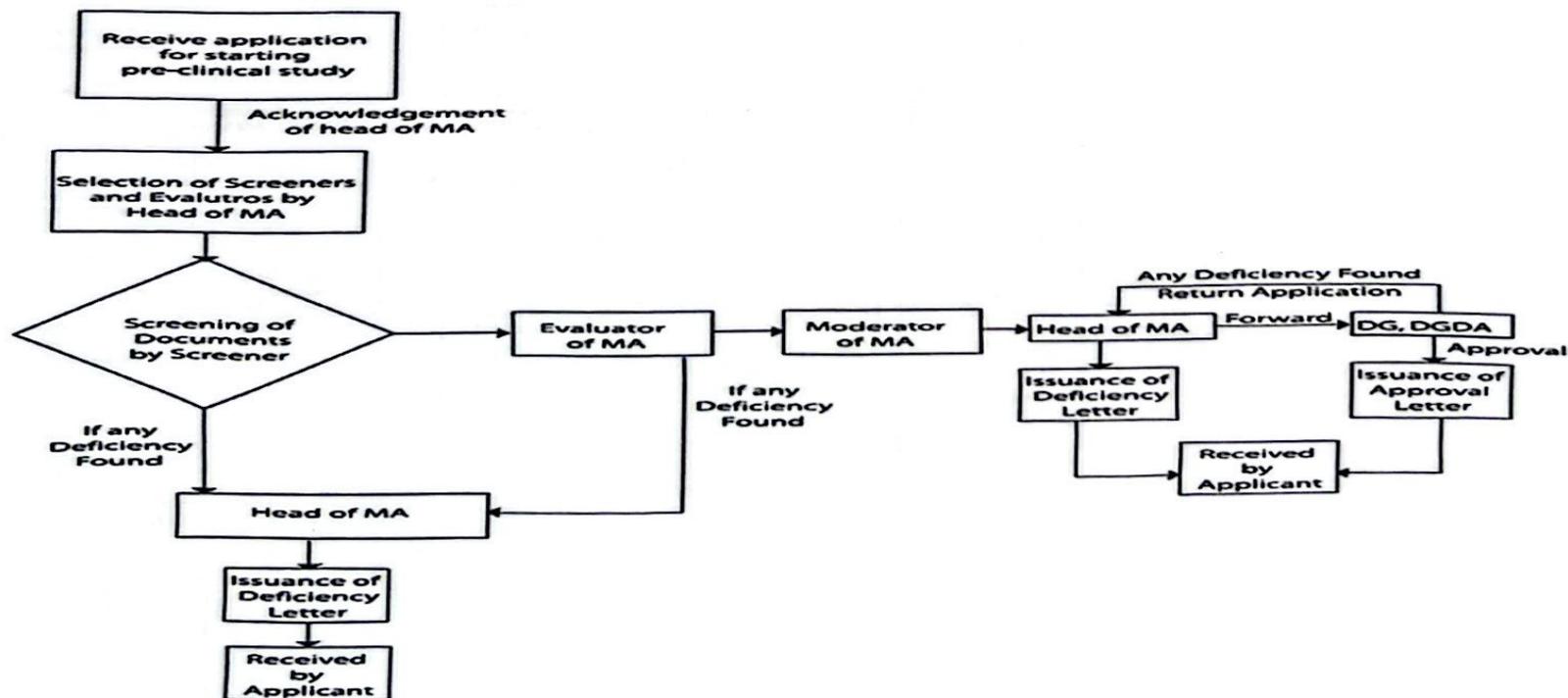


DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

Authorized Personnel Only

| Annexure – 2 | | | | | | |
|---|--|----------------|-------------|---|----------|---|
|  | FORM Title: Flowchart for the registration procedure for introduced vaccine and biological products manufactured in Bangladesh (Locally Developed Vaccine & Biological Bulk Antigen or Product) | | | | |  |
| Form No. | Version No. | Effective Date | Review Date | Approved by | Date | Page No. |
| NRA-MA-013/F02-02 | 06 | JAN' 25 | JAN' 29 |  | 10.12.24 | 04 of 07 |

Approval to Perform Clinical Trials

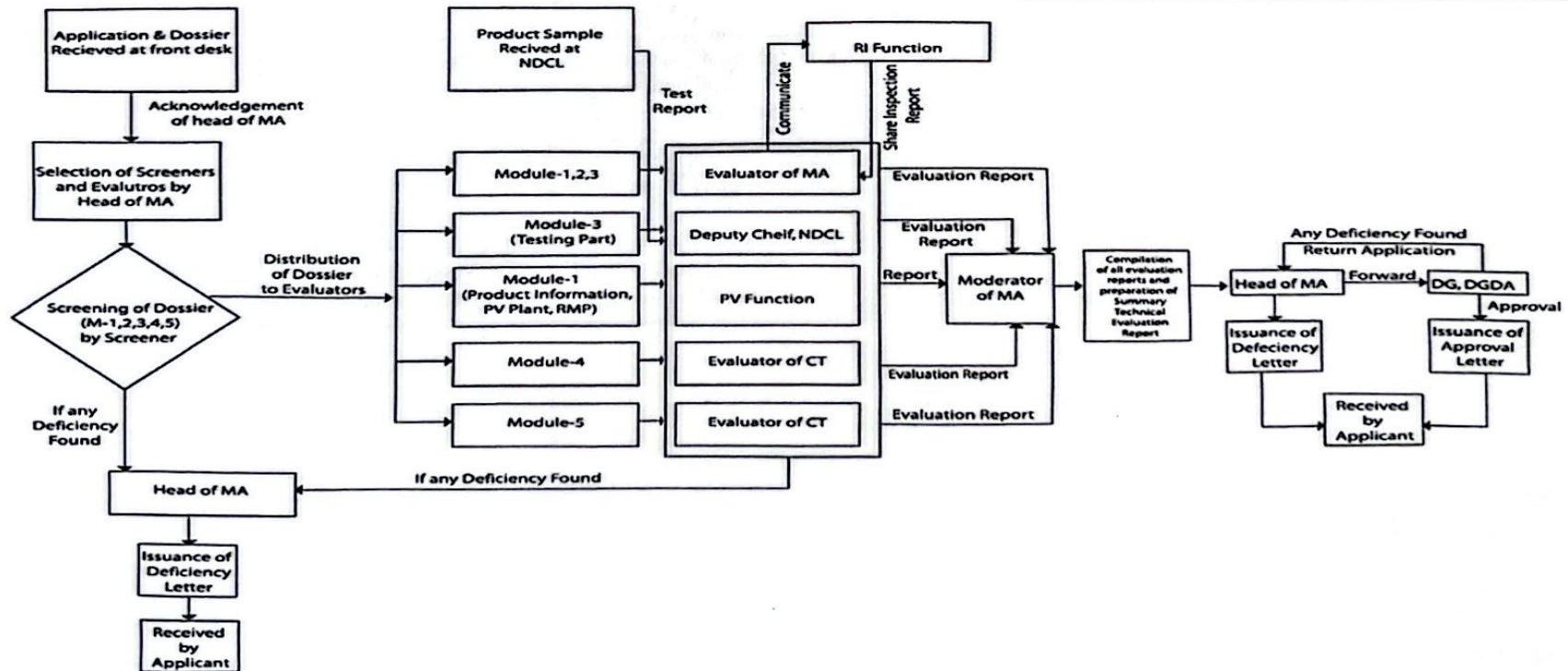


DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

Authorized Personnel Only

| Annexure – 2 | | | | | | |
|---|--|----------------|-------------|---|----------|---|
|  | FORM Title: Flowchart for the registration procedure for introduced vaccine and biological products manufactured in Bangladesh (Locally Developed Vaccine & Biological Bulk Antigen or Product) | | | | |  |
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Registration Procedure for Introduced Vaccine using Indigenous or locally developed bulk



DIRECTORATE GENERAL OF DRUG ADMINISTRATION

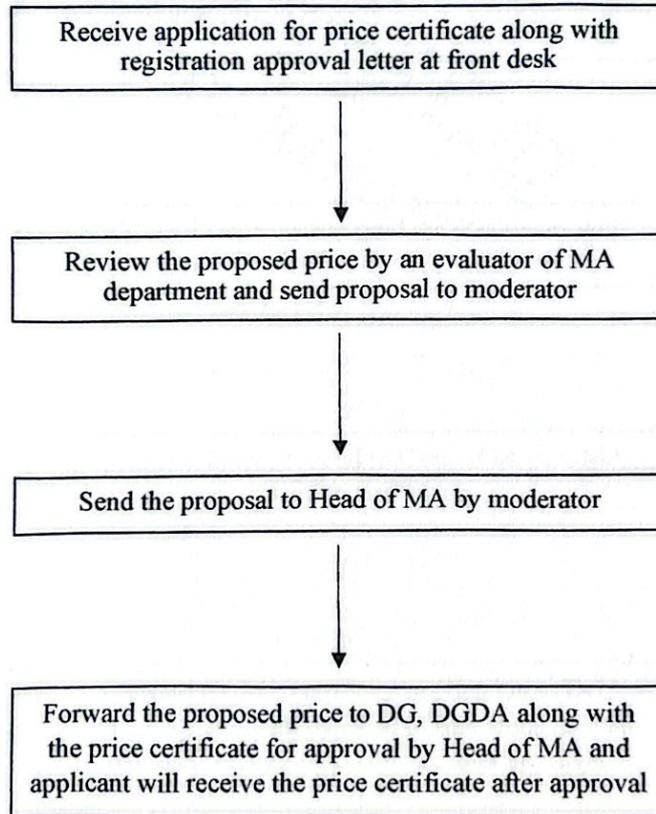
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

Authorized Personnel Only

Annexure-2

| | | | | | | |
|---|--|----------------|-------------|--|----------|---|
|  | FORM Title: Flowchart for the registration procedure for introduced vaccine and biological products manufactured in Bangladesh (Locally Developed Vaccine & Biological Bulk Antigen or Product) | | | | |  |
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Price certificate issuance



Tentative time needed to execute price certificate issuance is 07 days. Calculation of tentative time depends on as per submission of applicant's consecutive deficient documents.

DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

Authorized Personnel Only

Annexure-2

| | | | | | | |
|---|--|----------------|-------------|--|----------|---|
|  | FORM Title: Flowchart for the registration procedure for introduced vaccine and biological products manufactured in Bangladesh (Locally Developed Vaccine & Biological Bulk Antigen or Product) | | | | |  |
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MA certificate

Receive application for MA certificate along with registration approval letter & Price certificate at front desk

Check the documents and send the documents with forwarding to moderator by an Evaluator of MA

Moderator will recommend to Head of MA for MA certificate issuance

Forward the MA certificate application to DG, DGDA for approval by Head of MA and applicant will receive the MA certificate after approval

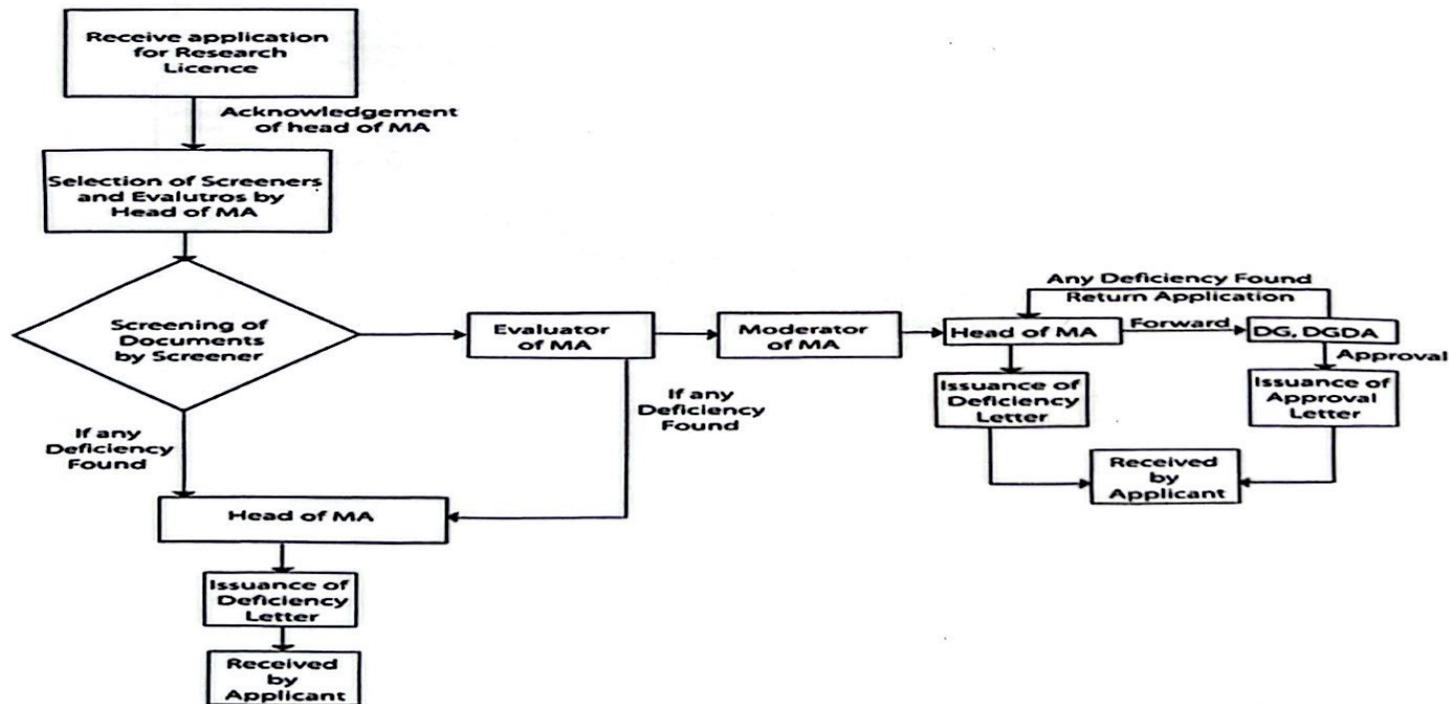
Tentative time needed to execute MA certificate issuance is 15 days. Calculation of tentative time depends on as per submission of applicant's consecutive deficient documents.

**DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH**

Authorized Personnel Only

| Annexure – 3 | | | | | | |
|---|--|----------------|-------------|---|----------|---|
|  | FORM Title: Flowchart for the registration procedure for Un-introduced or New vaccine and biological products in Bangladesh (Locally Developed Vaccine & Biological Bulk Antigen or Products) | | | | |  |
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Application for Research License



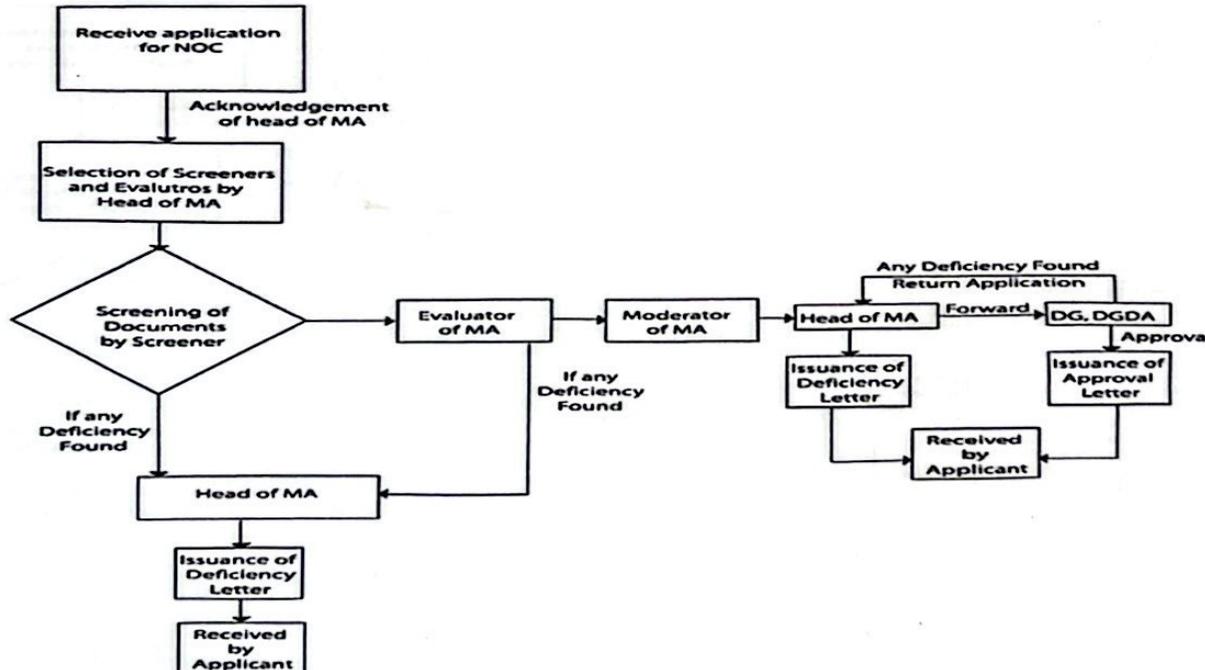
**DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH**

Authorized Personnel Only

Annexure – 3

| | | | | | | |
|---|--|----------------|-------------|---|----------|---|
|  | FORM Title: Flowchart for the registration procedure for introduced vaccine and biological products manufactured in Bangladesh (Locally Developed Vaccine & Biological Bulk Antigen or Product) | | | | |  |
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Issuance of NOC for Importation of any substances and cells

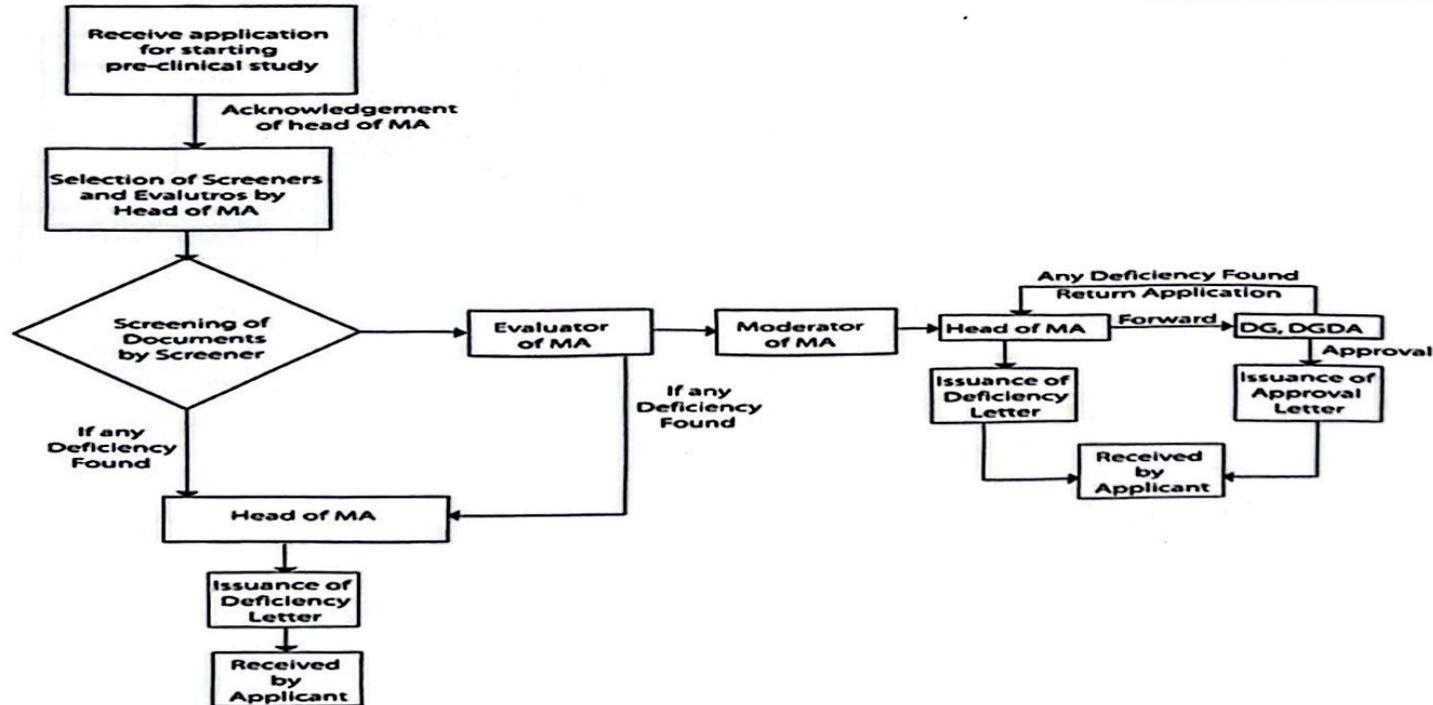


DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

Authorized Personnel Only

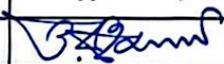
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|  | FORM Title: Flowchart for the registration procedure for introduced vaccine and biological products manufactured in Bangladesh (Locally Developed Vaccine & Biological Bulk Antigen or Product) | | | | |  |
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Approval to Perform Preclinical Study

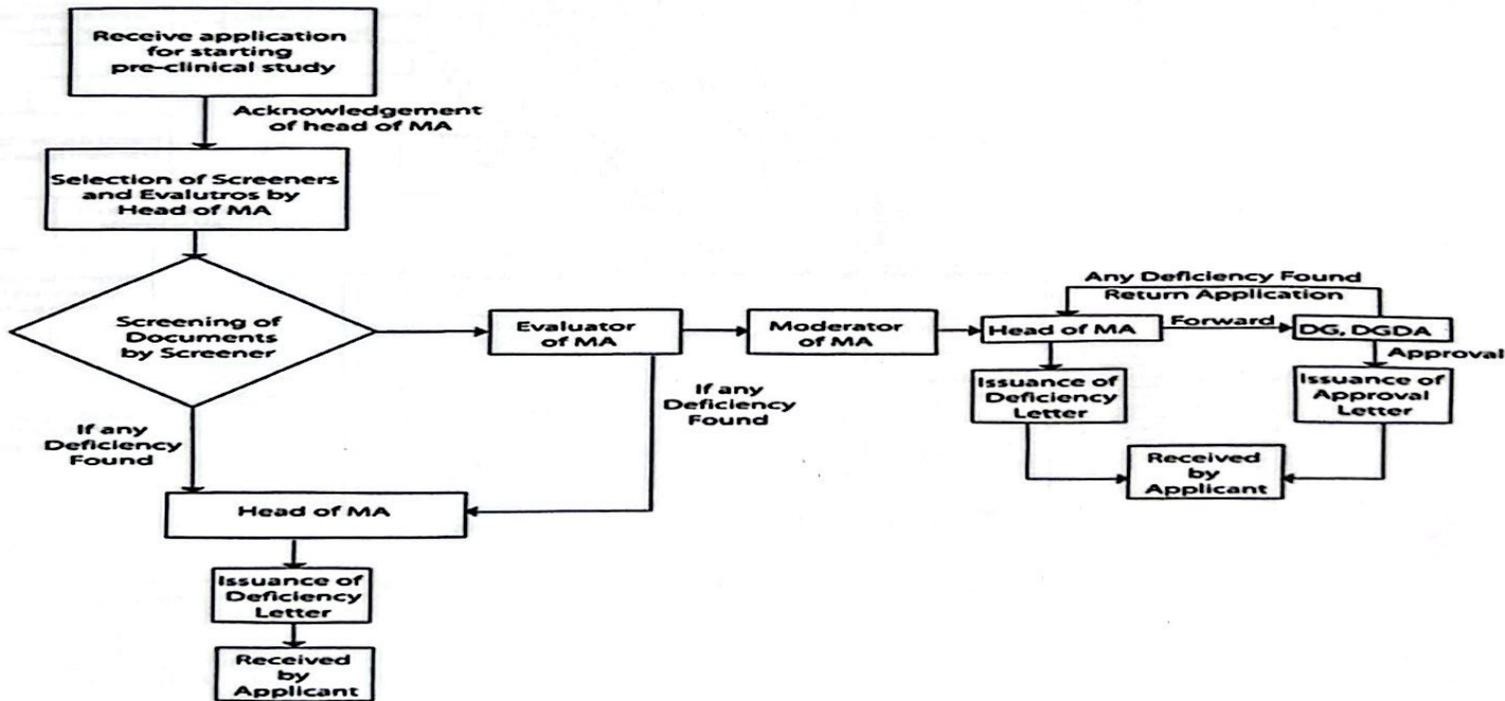


DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

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| Annexure – 3 | | | | | | |
|---|--|----------------|-------------|---|----------|---|
|  | FORM Title: Flowchart for the registration procedure for introduced vaccine and biological products manufactured in Bangladesh (Locally Developed Vaccine & Biological Bulk Antigen or Product) | | | | |  |
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Approval to Perform Clinical Trials

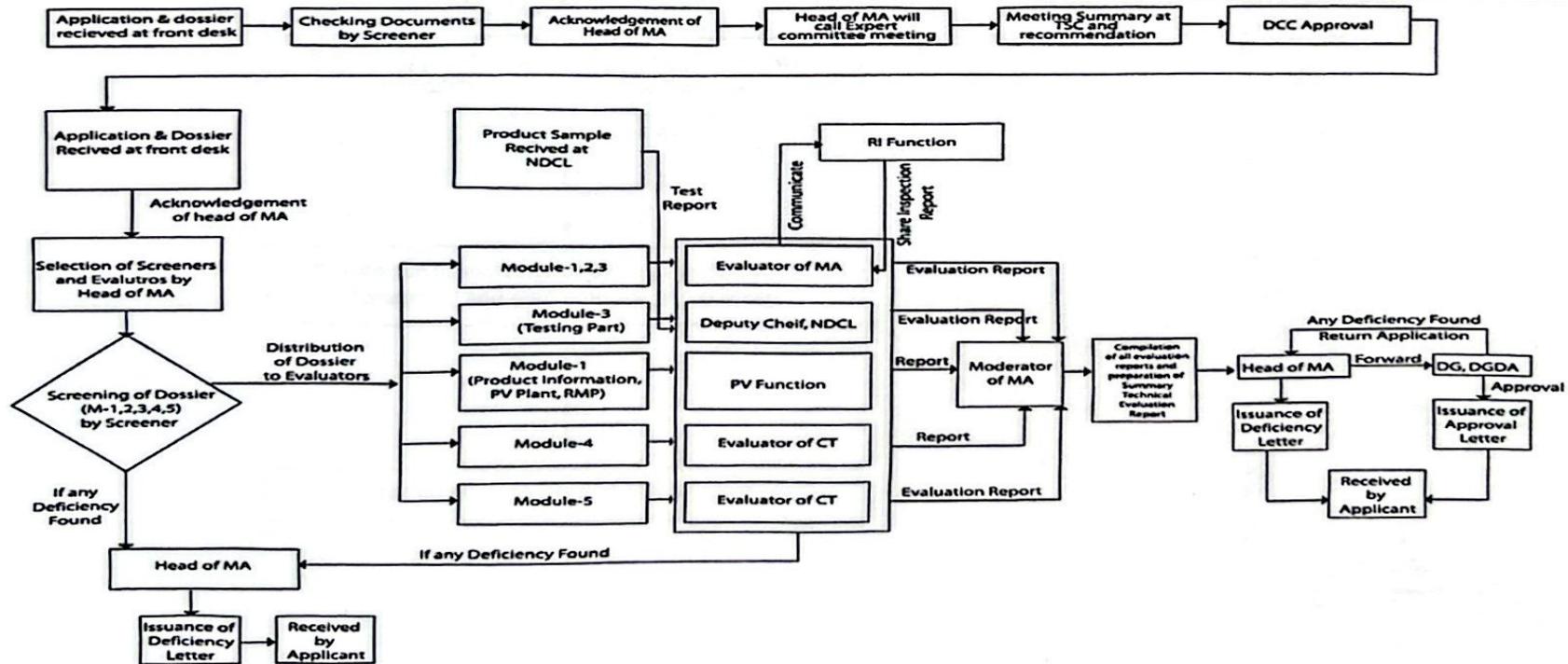


DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

Authorized Personnel Only

| Annexure – 3 | | | | | | |
|---|---|----------------|-------------|---|----------|---|
|  | FORM Title: Flowchart for the registration procedure for introduced vaccine and biological products manufactured in Bangladesh (Locally Developed Vaccine & Biological Bulk Antigen or Product) | | | | |  |
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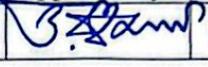
Registration Procedure for Un-Introduced Vaccine using Indigenous or locally developed bulk



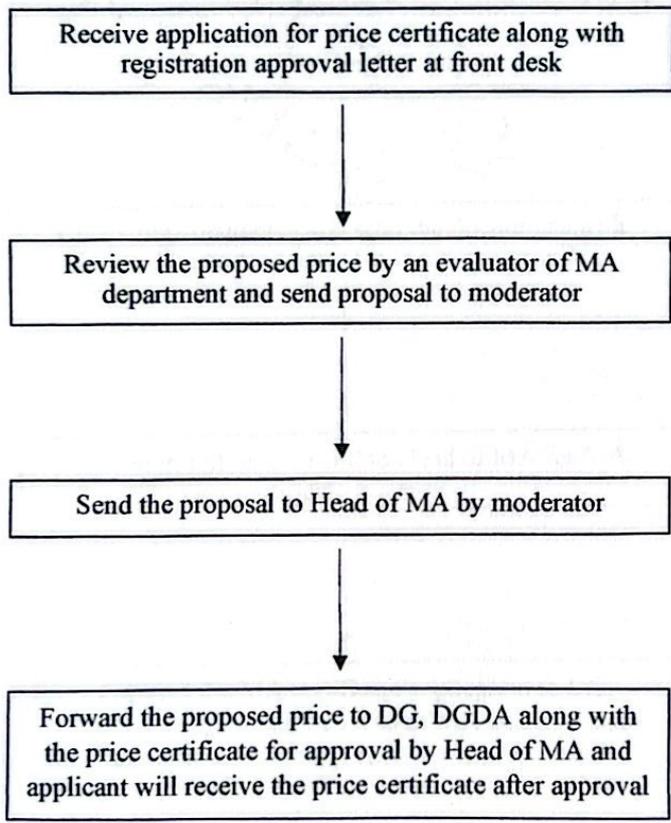
DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

Authorized Personnel Only

Annexure-3

| | | | | | | |
|---|--|----------------|-------------|--|----------|---|
|  | FORM Title: Flowchart for the registration procedure for Un-introduced or New vaccine and biological products in Bangladesh (Locally Developed Vaccine & Biological Bulk Antigen or Products) | | | | |  |
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Price certificate issuance



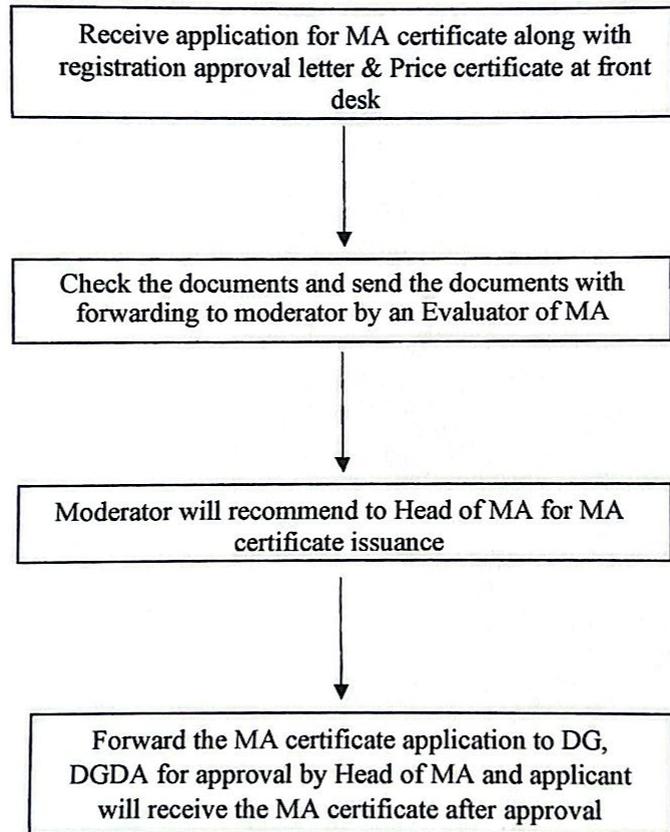
Tentative time needed to execute price certificate issuance is 07 days. Calculation of tentative time depends on as per submission of applicant's consecutive deficient documents.

DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

Authorized Personnel Only

| Annexure-3 | | | | | | |
|---|--|----------------|-------------|--|----------|---|
|  | FORM Title: Flowchart for the registration procedure for Un-introduced or New vaccine and biological products in Bangladesh (Locally Developed Vaccine & Biological Bulk Antigen or Products) | | | | |  |
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MA certificate



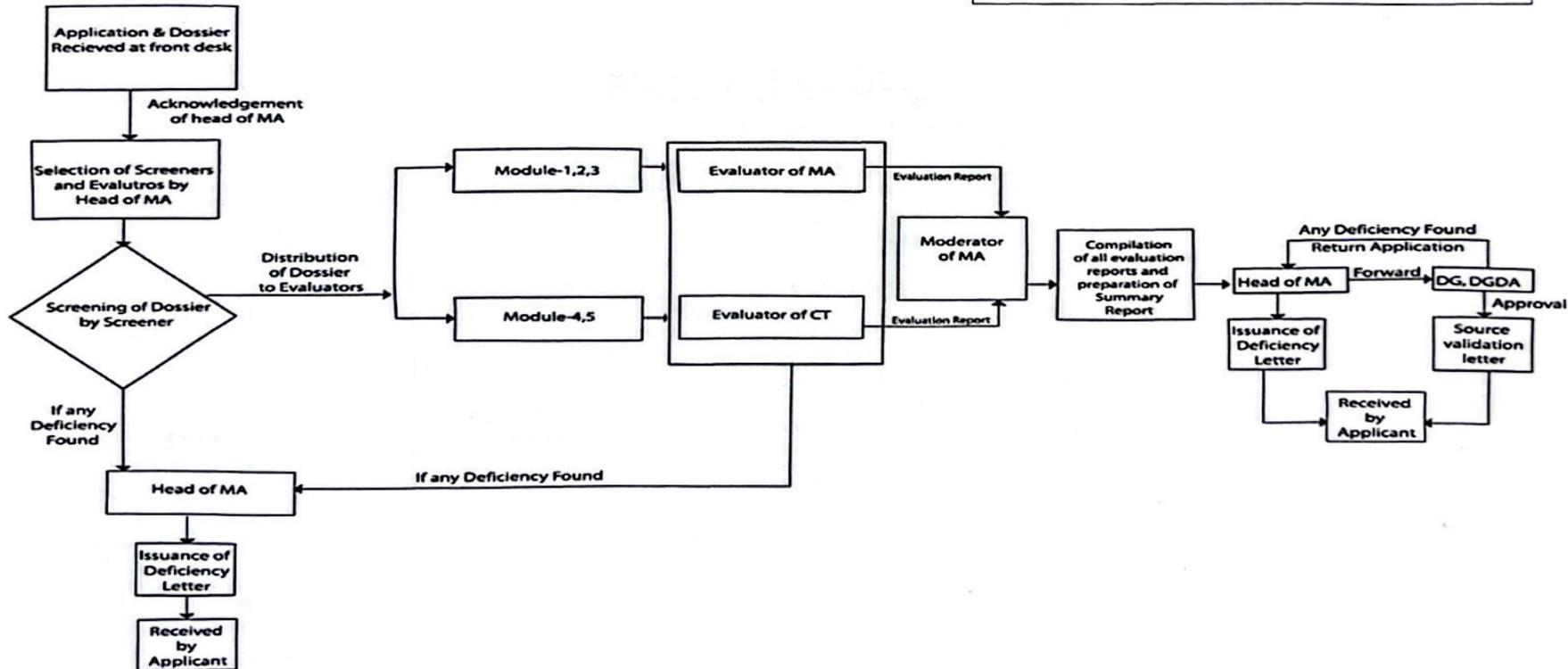
Tentative time needed to execute MA certificate issuance is 15 days. Calculation of tentative time depends on as per submission of applicant's consecutive deficient documents.

**DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH**

Authorized Personnel Only

| Annexure – 4 | | | | | | |
|---|---|----------------|-------------|---|----------|---|
|  | FORM Title: Flowchart for the registration procedure of Un-introduced or new vaccine and biological products in Bangladesh (Locally manufactured product by using imported bulk) | | | | |  |
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Source Validation of Vaccine and Biological Products

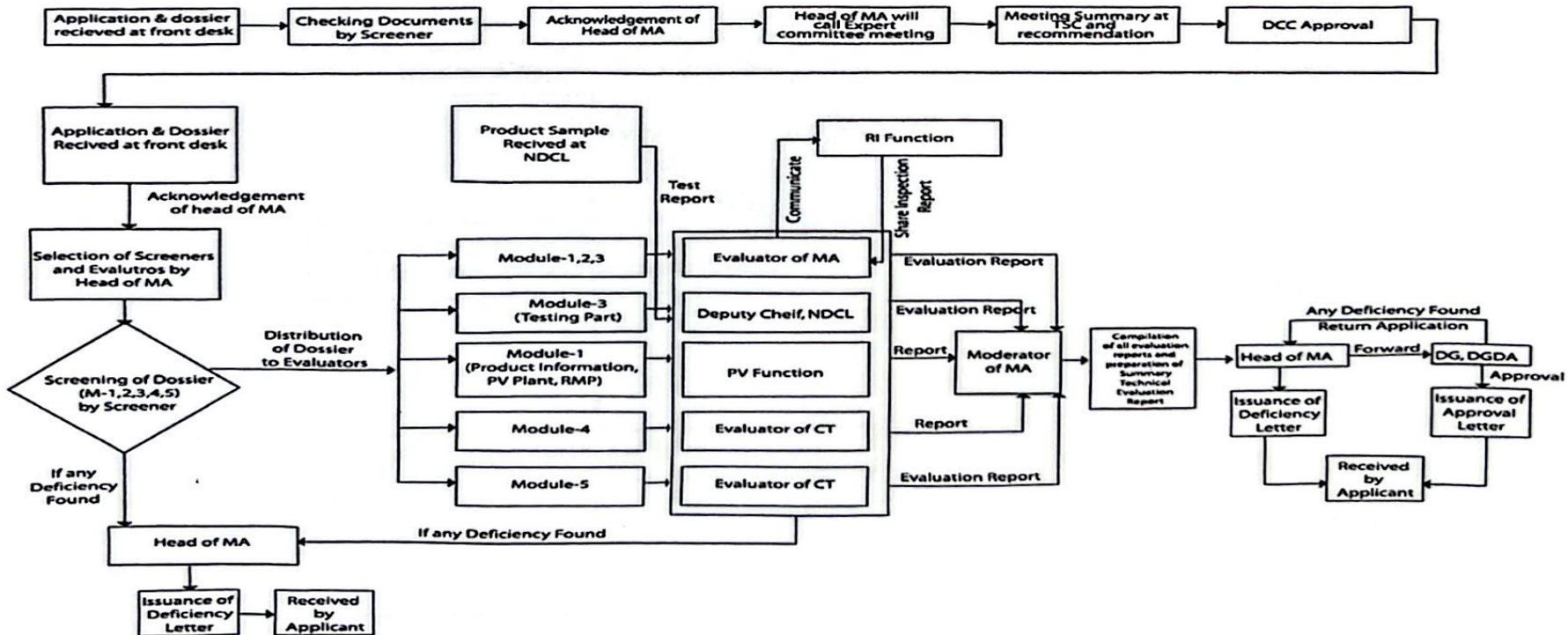


DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

Authorized Personnel Only

| Annexure – 4 | | | | | | |
|---|---|----------------|-------------|---|----------|---|
|  | FORM Title: Flowchart for the registration procedure of Un-introduced or new vaccine and biological products in Bangladesh (Locally manufactured product by using imported bulk) | | | | |  |
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Registration procedure of Un-introduced vaccine and biological products using imported bulk

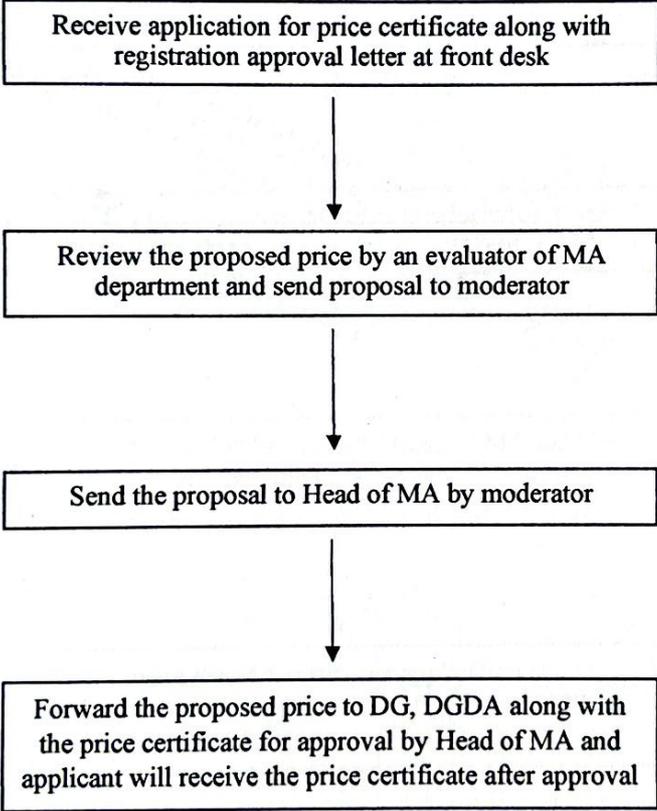


DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

Authorized Personnel Only

| Annexure-4 | | | | | | |
|---|---|----------------|-------------|--|----------|---|
|  | FORM Title: Flowchart for the registration procedure of Un-introduced or new vaccine and biological products in Bangladesh (Locally manufactured product by using imported bulk) | | | | |  |
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Price certificate issuance



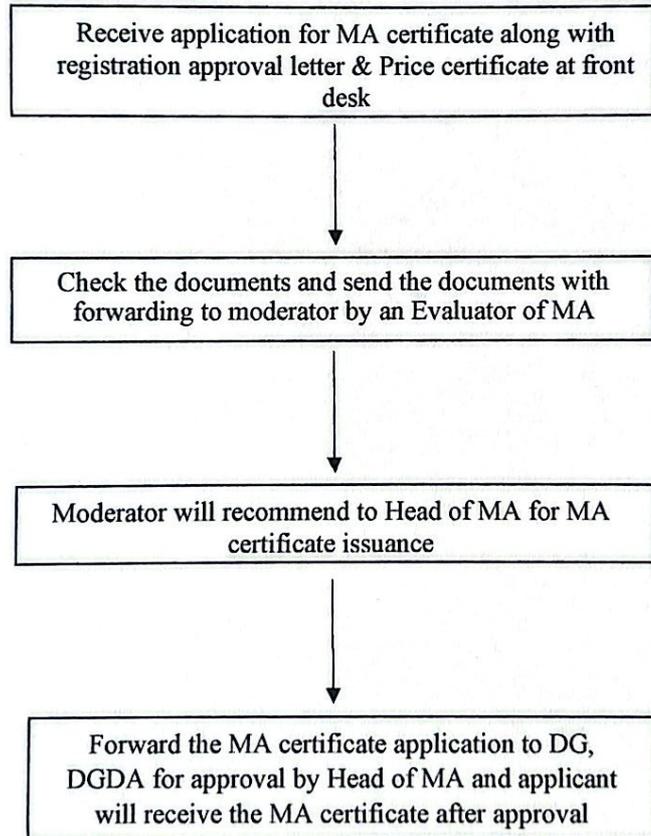
Tentative time needed to execute price certificate issuance is 07 days. Calculation of tentative time depends on as per submission of applicant's consecutive deficient documents.

DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

Authorized Personnel Only

| Annexure-4 | | | | | | |
|---|---|----------------|-------------|--|----------|---|
|  | FORM Title: Flowchart for the registration procedure of Un-introduced or new vaccine and biological products in Bangladesh (Locally manufactured product by using imported bulk) | | | | |  |
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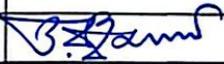
MA certificate



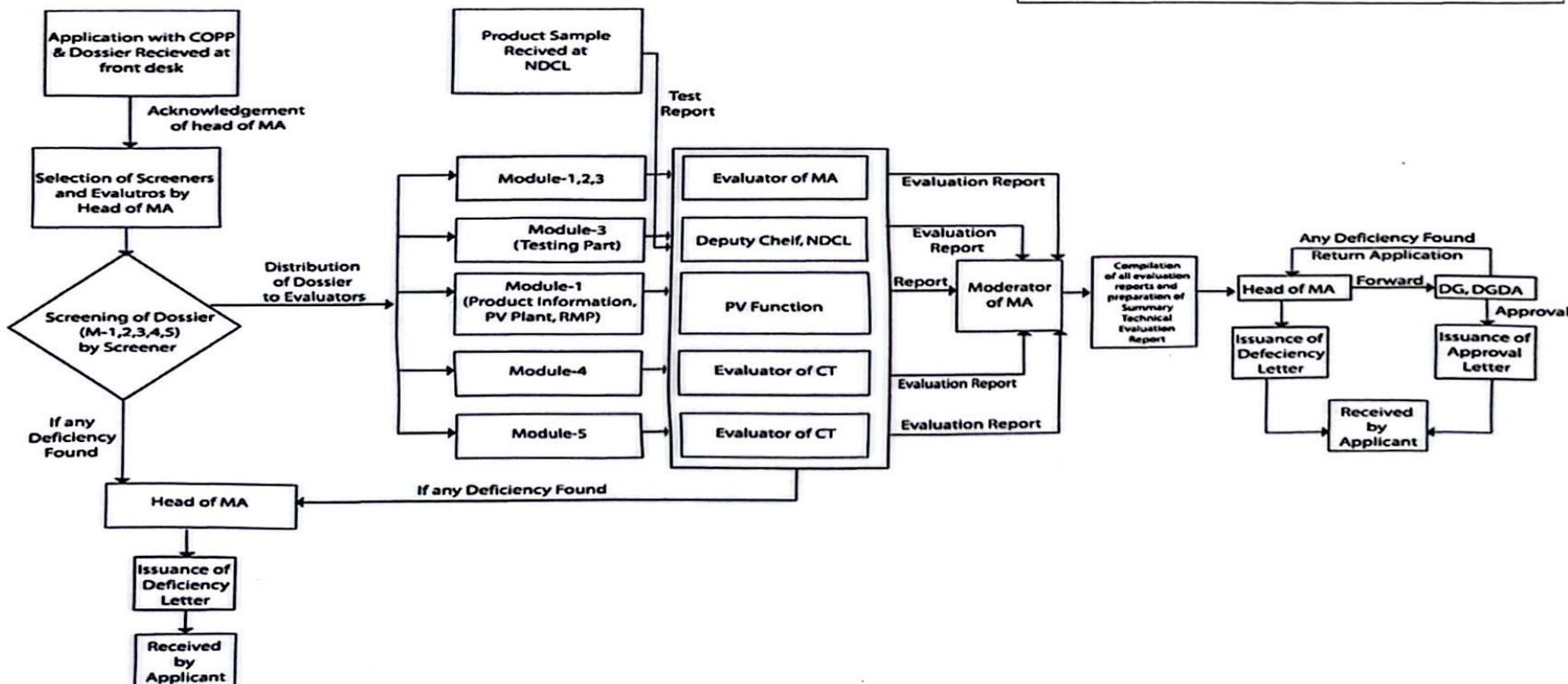
Tentative time needed to execute MA certificate issuance is 15 days. Calculation of tentative time depends on as per submission of applicant's consecutive deficient documents.

DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

Authorized Personnel Only

| Annexure – 5 | | | | | | |
|---|--|----------------|-------------|---|----------|---|
|  | FORM Title: Flowchart for the registration procedure for introduced vaccine and biological products in Bangladesh (For Imported finished Product) | | | | |  |
| Form No. | Version No. | Effective Date | Review Date | Approved by | Date | Page No. |
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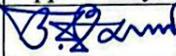
Registration procedure for introduced Vaccine and biological products as Imported finished product



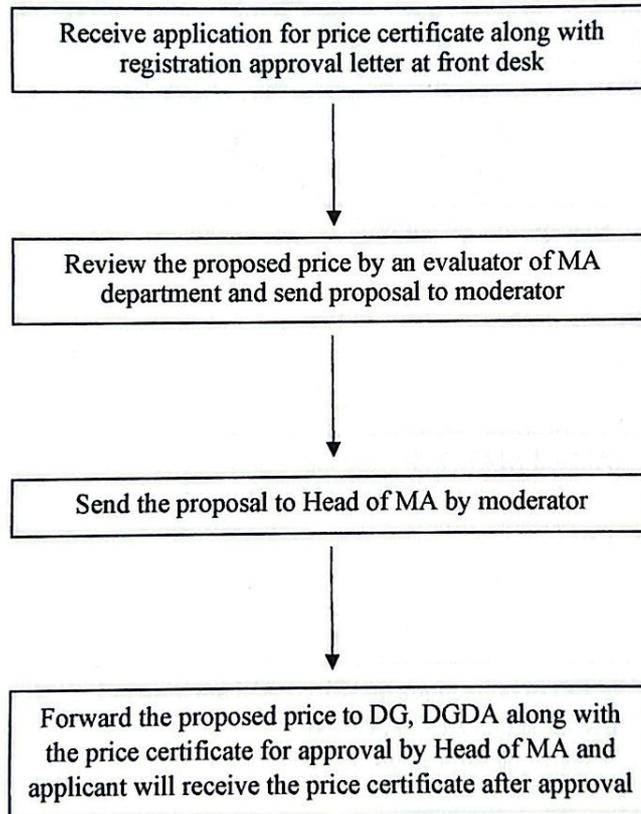
DIRECTORATE GENERAL OF DRUG ADMINISTRATION

MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

Authorized Personnel Only

| Annexure-5 | | | | | | |
|---|--|----------------|-------------|--|----------|---|
|  | FORM Title: Flowchart for the registration procedure for introduced vaccine and biological products in Bangladesh (For imported Finished Product) | | | | |  |
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Price certificate issuance



Tentative time needed to execute price certificate issuance is 07 days. Calculation of tentative time depends on as per submission of applicant's consecutive deficient documents.

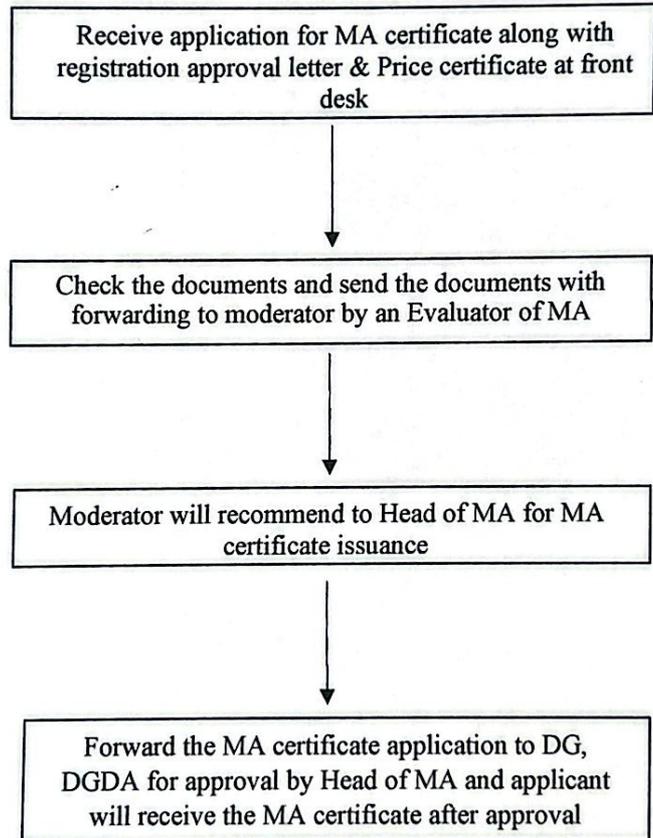
DIRECTORATE GENERAL OF DRUG ADMINISTRATION

MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

Authorized Personnel Only

| Annexure-5 | | | | | | |
|---|--|----------------|-------------|--|----------|---|
|  | FORM Title: Flowchart for the registration procedure for introduced vaccine and biological products in Bangladesh (For imported Finished Product) | | | | |  |
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MA certificate

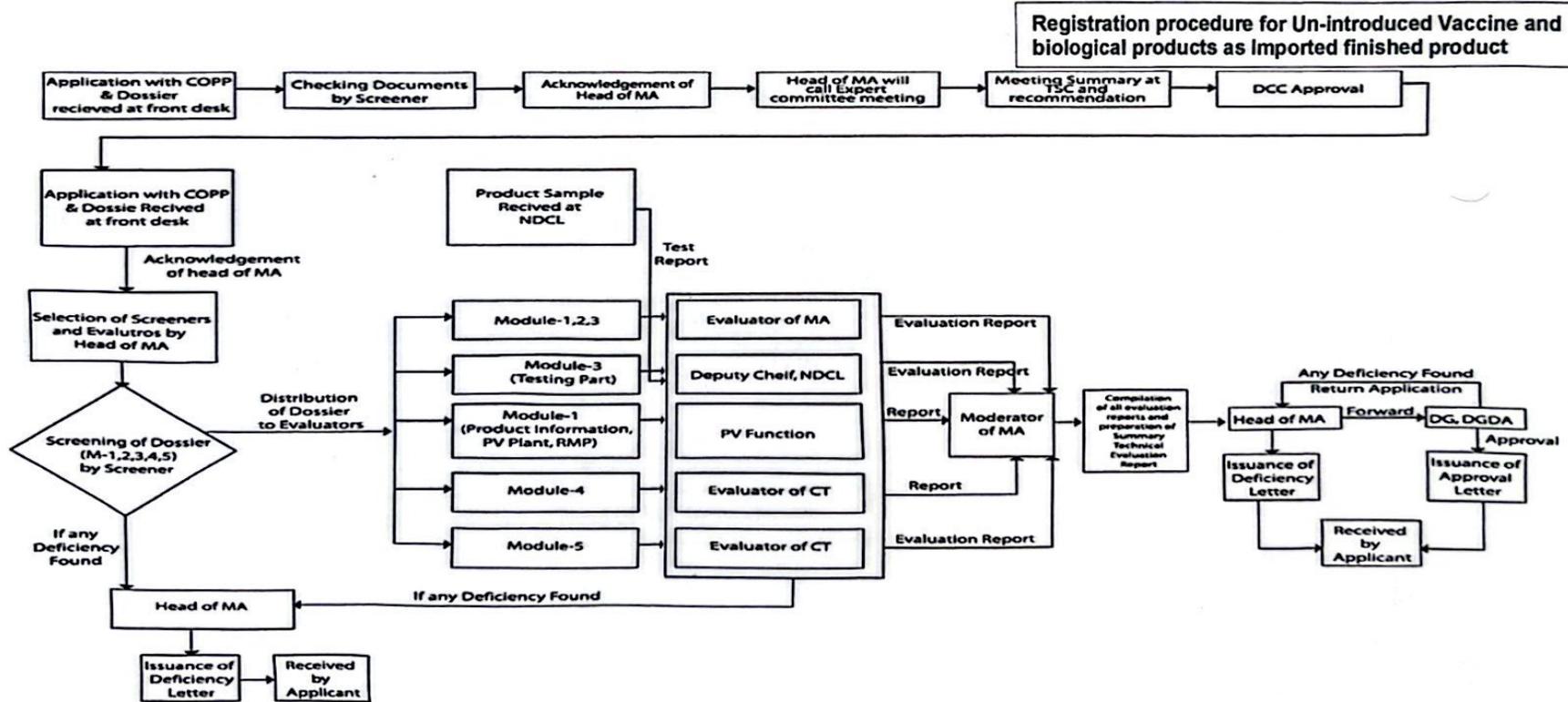


Tentative time needed to execute MA certificate issuance is 15 days. Calculation of tentative time depends on as per submission of applicant's consecutive deficient documents.

**DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH**

Authorized Personnel Only

| Annexure – 6 | | | | | | |
|---|--|----------------|-------------|---|----------|---|
|  | FORM Title: Flowchart for the registration procedure for Un-introduced or New vaccine and biological products in Bangladesh (For Imported finished Product) | | | | |  |
| Form No. | Version No. | Effective Date | Review Date | Approved by | Date | Page No. |
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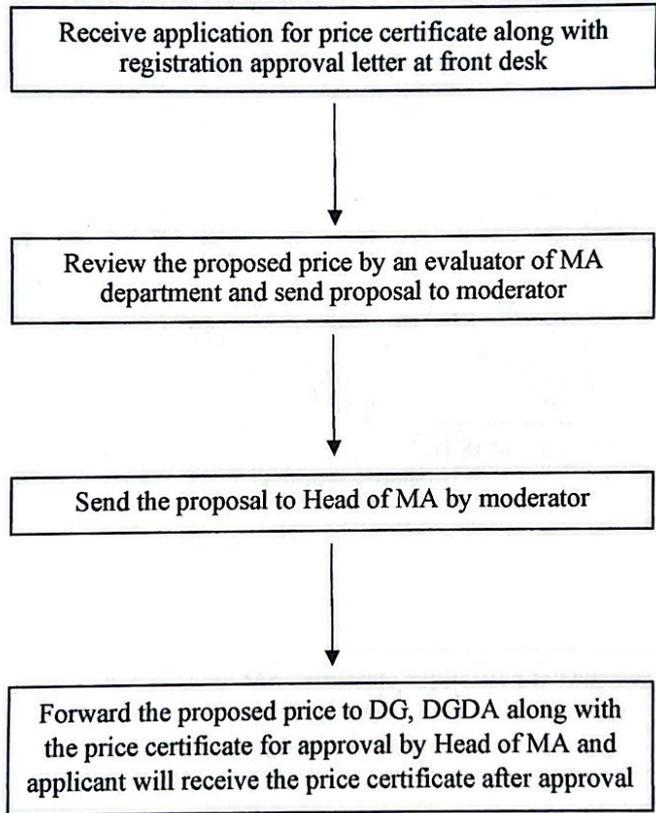


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MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

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| Annexure-6 | | | | | | |
|---|---|----------------|-------------|--|----------|---|
|  | FORM Title: Flowchart for the registration procedure for Un-introduced or new vaccine and biological products in Bangladesh (For imported Product) | | | | |  |
| Form No. | Version No. | Effective Date | Review Date | Approved by | Date | Page No. |
| NRA-MA-013/F06-02 | 06 | JAN' 25 | JAN' 29 |  | 10.12.24 | 02 of 03 |

Price certificate issuance



Tentative time needed to execute price certificate issuance is 07 days. Calculation of tentative time depends on as per submission of applicant's consecutive deficient documents.

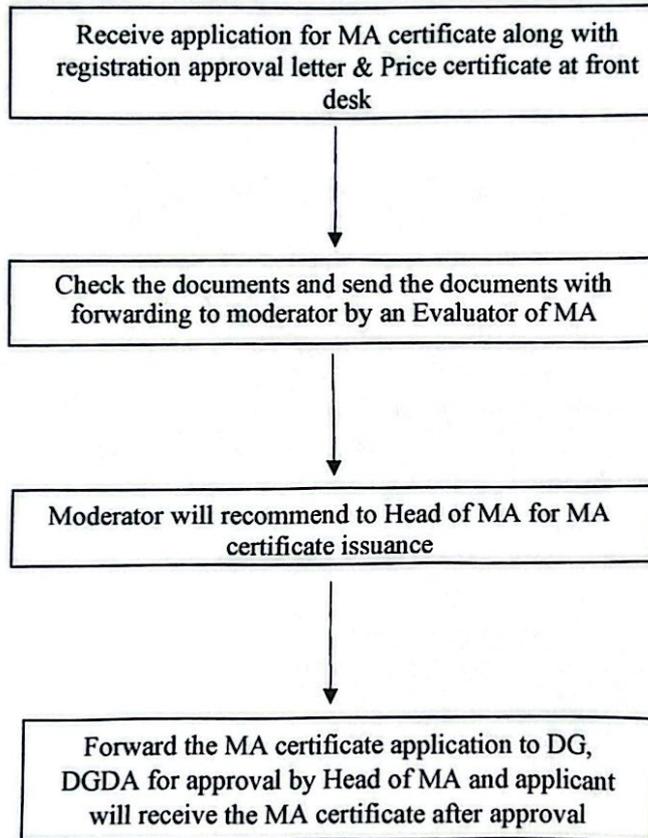
DIRECTORATE GENERAL OF DRUG ADMINISTRATION

MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

Authorized Personnel Only

| Annexure-6 | | | | | | |
|---|---|----------------|-------------|--|----------|---|
|  | FORM Title: Flowchart for the registration procedure for Un-introduced or new vaccine and biological products in Bangladesh (For imported Product) | | | | |  |
| Form No. | Version No. | Effective Date | Review Date | Approved by | Date | Page No. |
| NRA-MA-013/F06-02 | 06 | JAN' 25 | JAN' 29 |  | 10.12.24 | 03 of 03 |

MA certificate



Tentative time needed to execute MA certificate issuance is 15 days. Calculation of tentative time depends on as per submission of applicant's consecutive deficient documents.

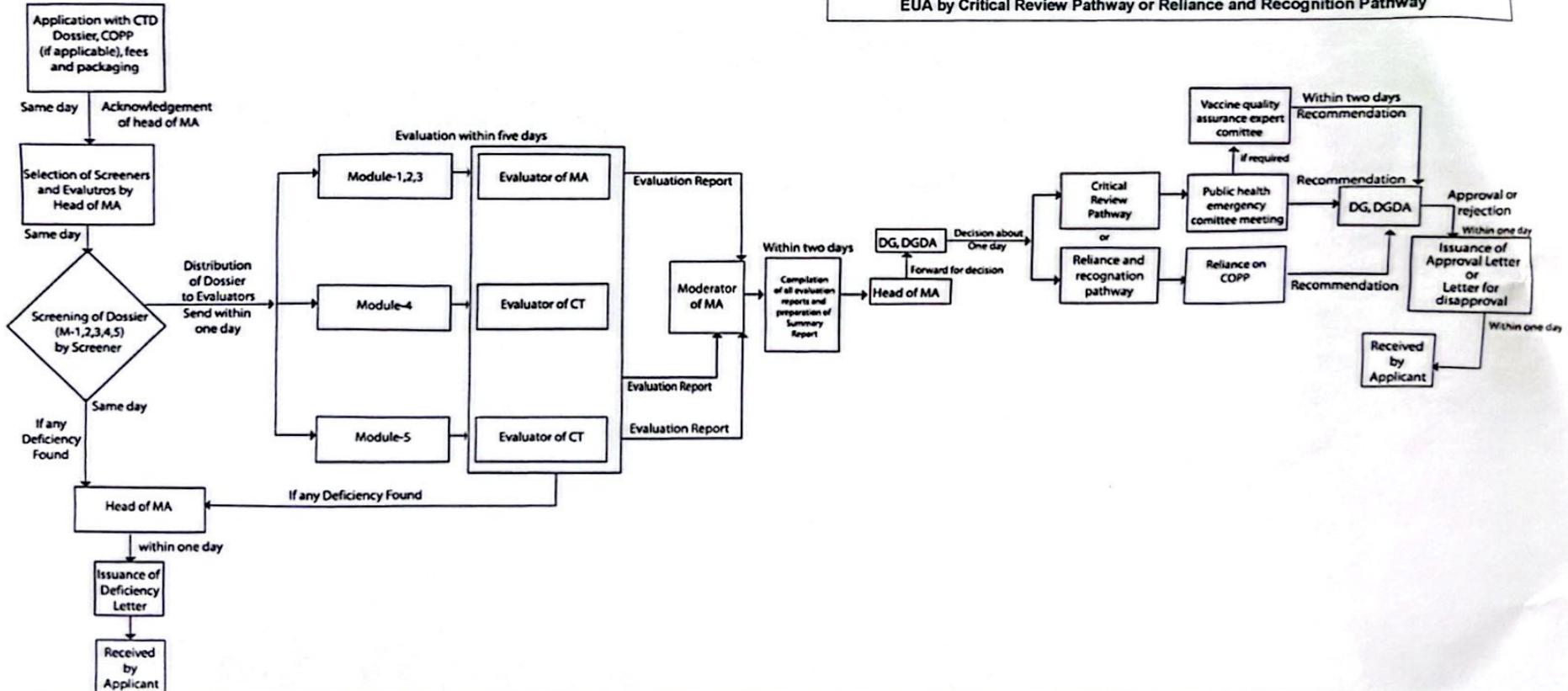
DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

Authorized Personnel Only

Annexure – 16

| | | | | | | |
|-------------------|--|----------------|-------------|-------------|----------|----------|
| | FORM Title: Flowchart for the registration procedure for Un-introduced or New vaccine and biological products in Bangladesh (For Imported finished Product) | | | | | |
| Form No. | Version No. | Effective Date | Review Date | Approved by | Date | Page No. |
| NRA-MA-013/F16-02 | 06 | JAN' 25 | JAN' 29 | | 10.12.24 | 01 of 01 |

EUA by Critical Review Pathway or Reliance and Recognition Pathway



Tentative time needs to execute up to EUA certificate issuance is 15 days. Calculation of tentative time depends on as per submission of applicant's consecutive deficient documents.