


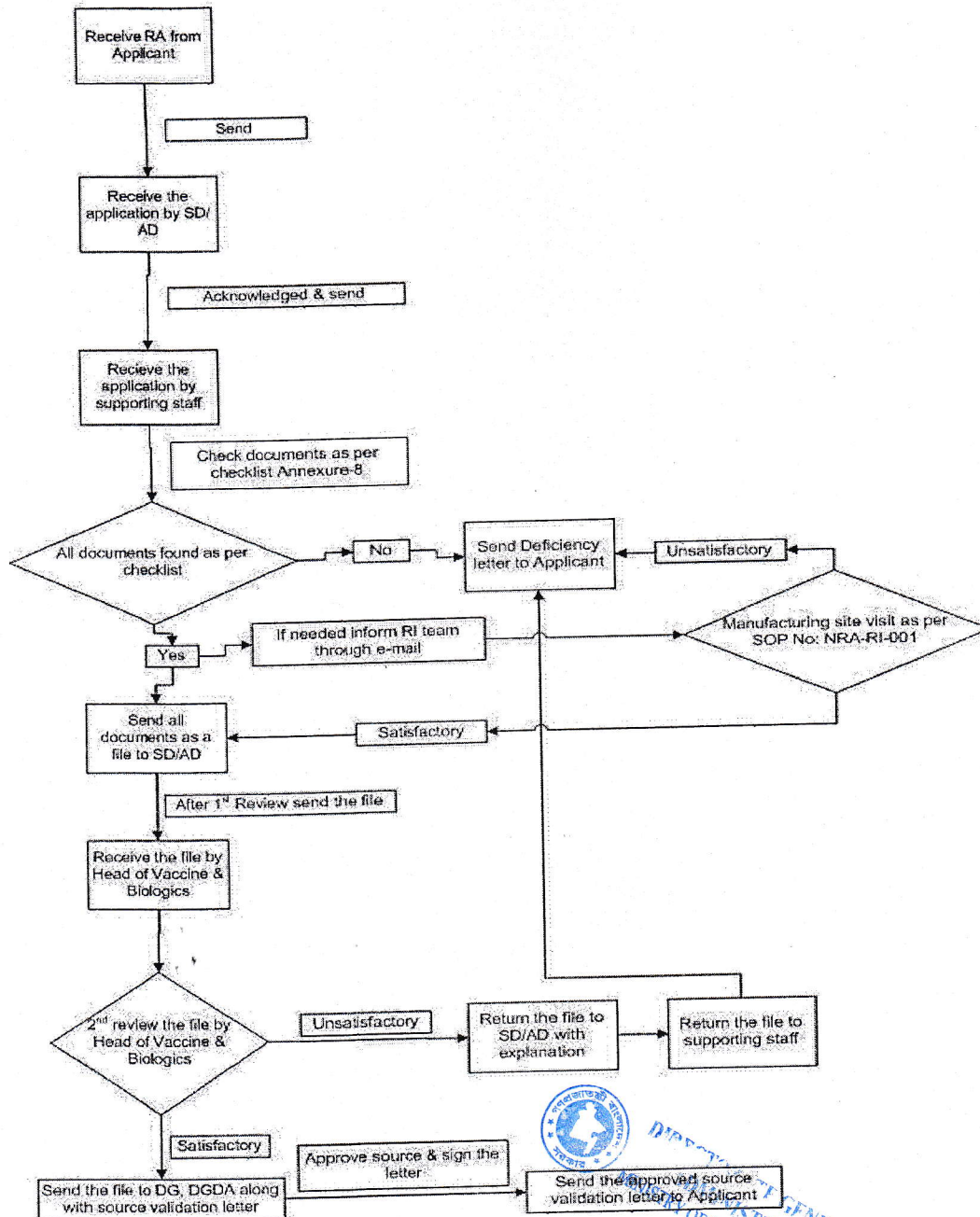



DIRECTORATE GENERAL OF DRUG ADMINISTRATION MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

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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	Authorized by	Date	Page No.
NRA-MA-013/F01-01	01	DEC' 21	DEC' 26		09.11.21	01 of 04

Source Validation







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 MINISTRY OF HEALTH AND FAMILY WELFARE

 BANGLADESH




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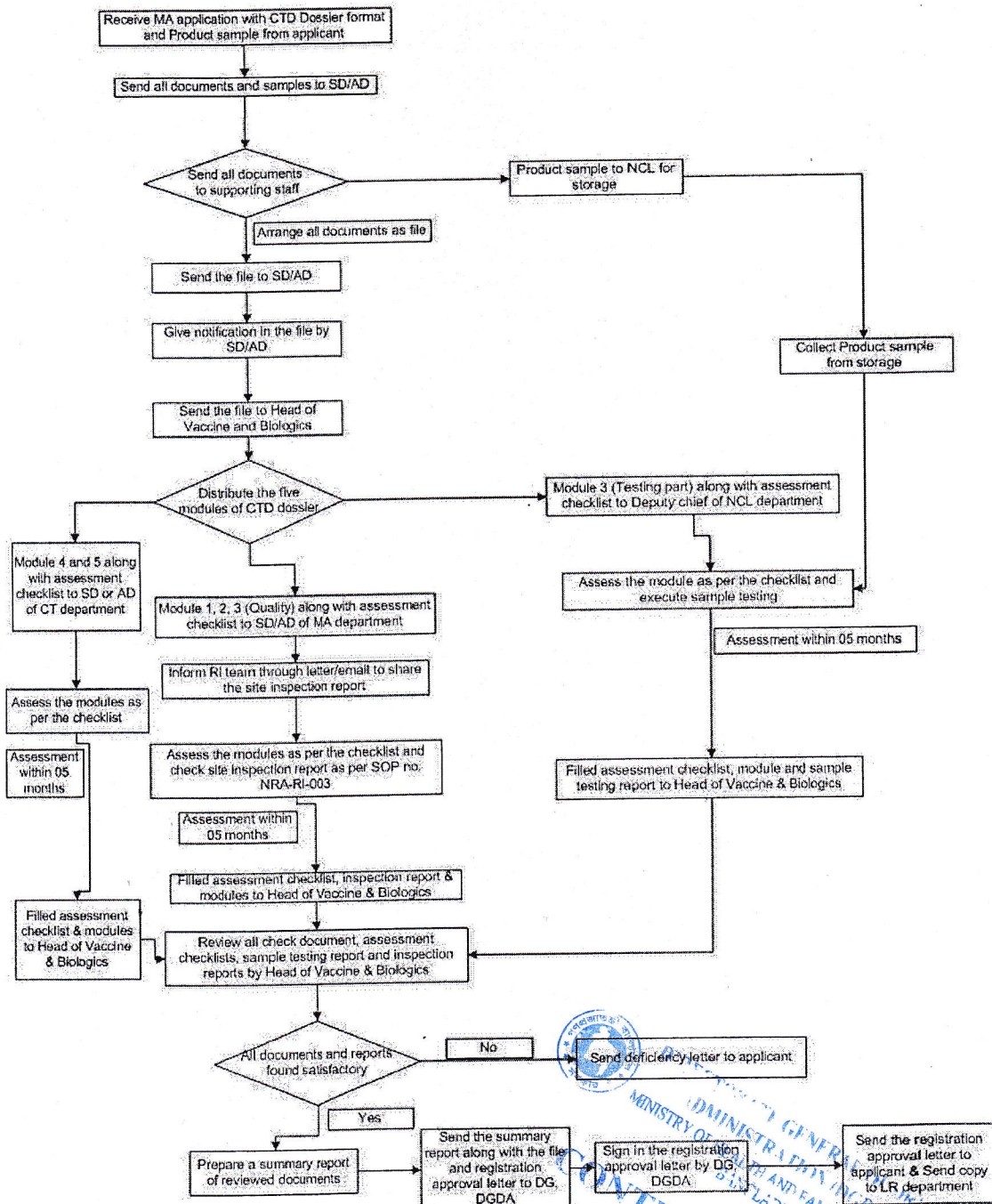



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Annexure – 1						
	FORM Title: Flowchart for the registration procedure for introduced vaccine and biological products manufactured in Bangladesh (Locally manufactured product by using imported bulk)					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-013/F01-01	01	DEC' 21	DEC' 26		09.11.21	02 of 04

Registration procedure for introduced vaccine using imported bulk.








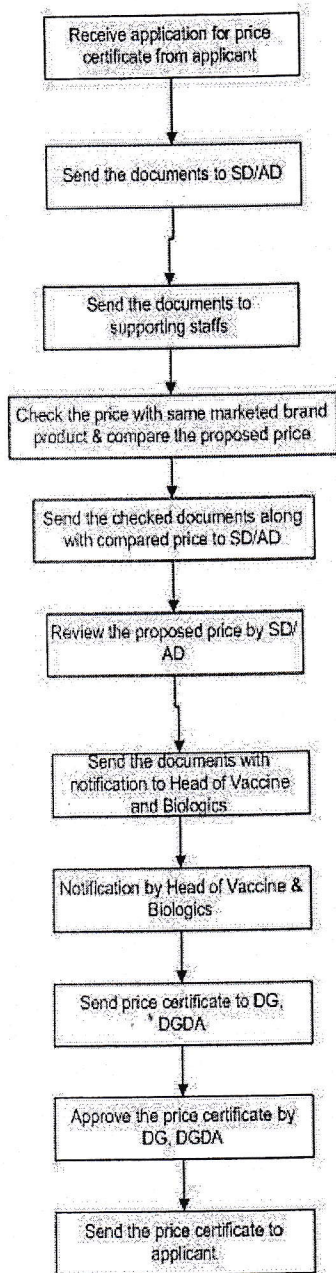
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MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

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Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-013/F01-01	01	DEC' 21	DEC' 26		09.11.21	03 of 04


Price certificate issuance




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




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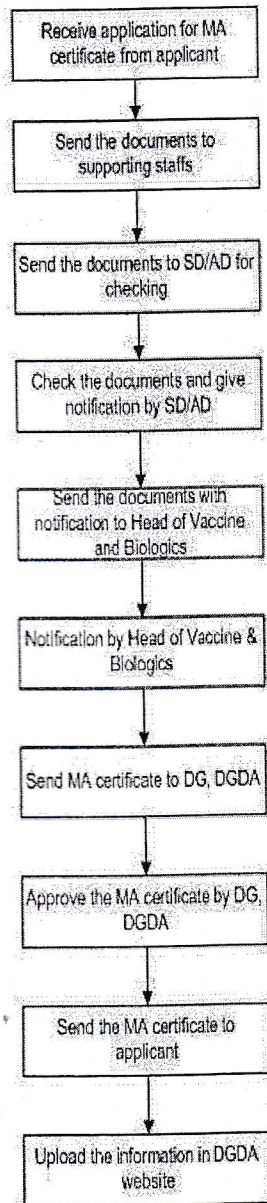


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MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH**

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	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	Authorized by	Date	Page No.
NRA-MA-013/F01-01	01	DEC' 21	DEC' 26		09.11.21	04 of 04

MA certificate Issuance






Tentative time need to execute up to MA certificate issuance is maximum 06 months. Calculation of tentative time depends on as per submission of applicant's consecutive deficient documents.


 DIRECTORATE GENERAL OF DRUGS
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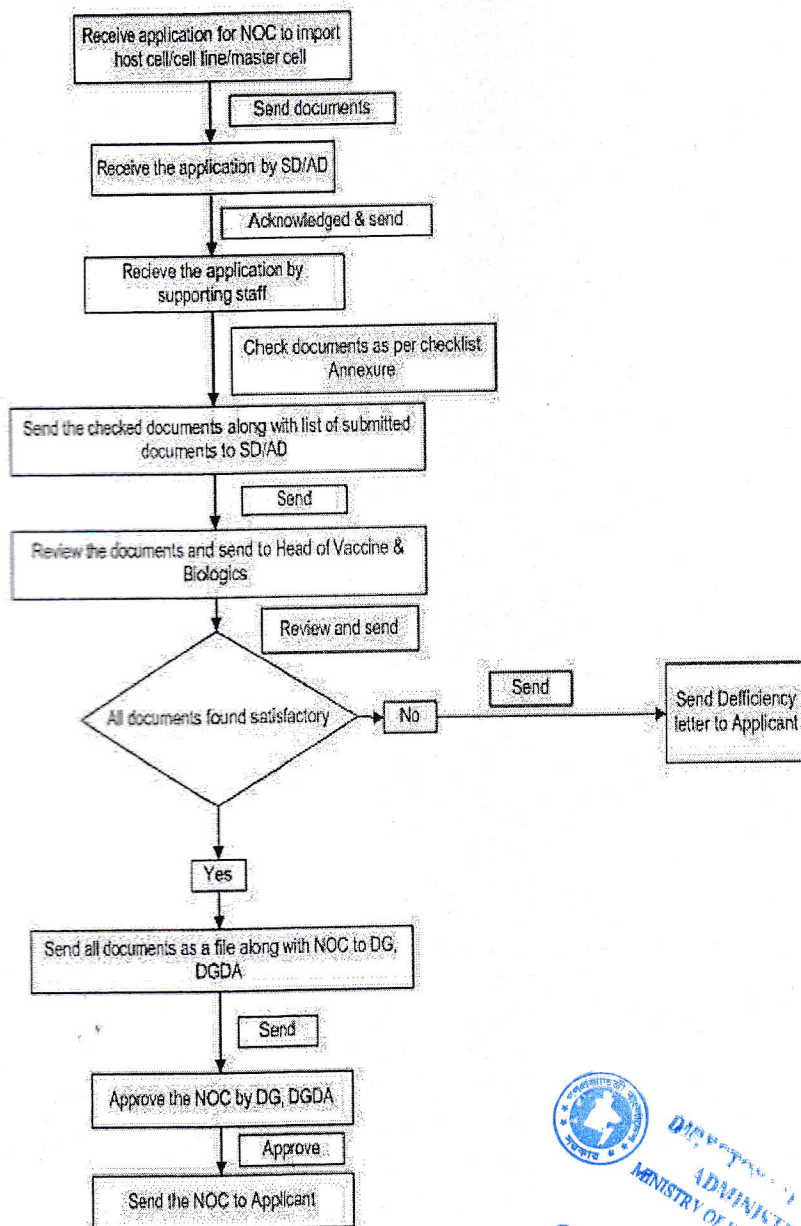

DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

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Annexure – 2

	FORM Title: Flowchart for the registration procedure for introduced vaccine and biological products manufactured in Bangladesh (Locally developed product by using Master seed)					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-013/F02-01	01	DEC' 21	DEC' 26		09.11.21	01 of 06

NOC to import host cell/cell line/master cell





Tentative time need to execute for NOC or permission letter issuance is maximum 03 days. Calculation of tentative time depends on as per submission of applicant's consecutive deficient documents.


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 MINISTRY OF HEALTH AND FAMILY WELFARE
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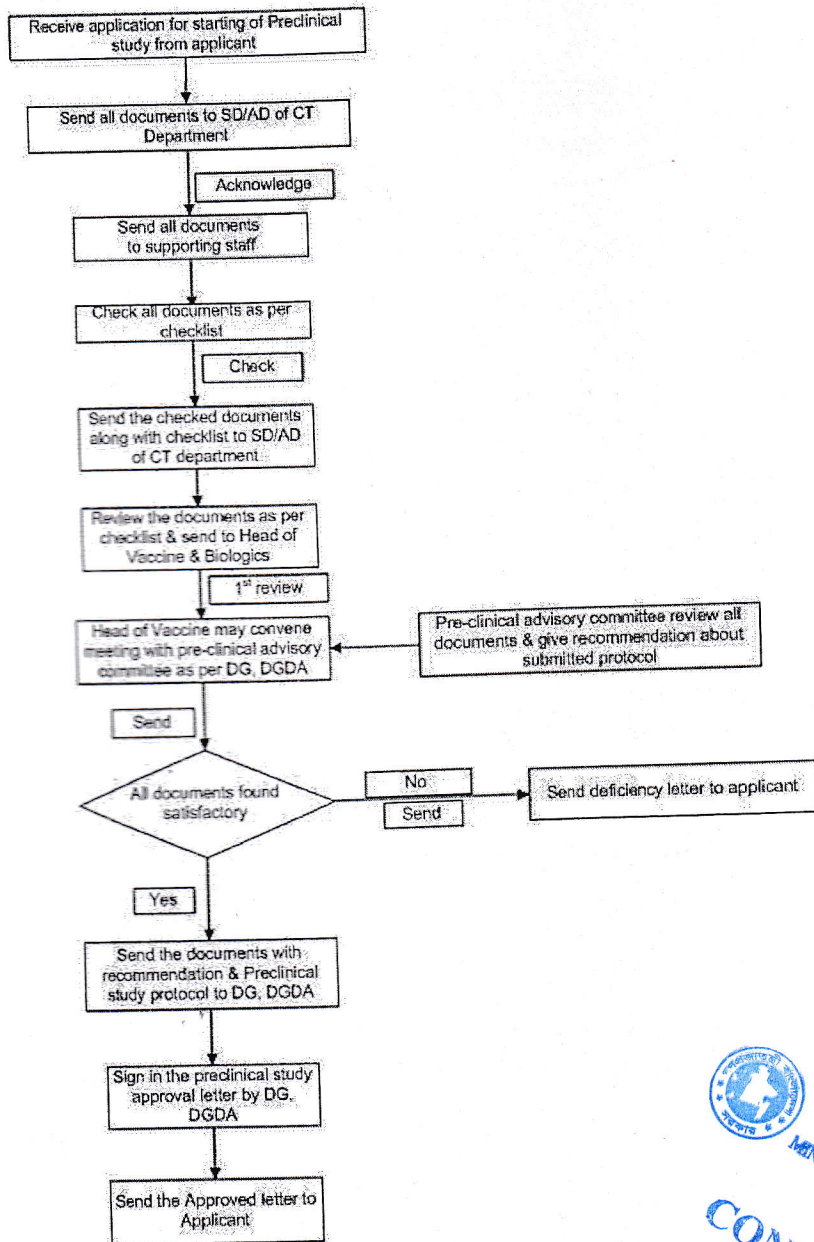
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MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

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Annexure - 2

	FORM Title: Flowchart for the registration procedure for introduced vaccine and biological products manufactured in Bangladesh (Locally developed product by using Master seed)					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-013/F02-01	01	DEC' 21	DEC' 26	<i>[Signature]</i>	09.11.21	02 of 06

NOC to start of preclinical study






Tentative time need to execute for Approval letter issuance is maximum 45 days. Calculation of tentative time depends on as per submission of applicant's consecutive deficient documents.

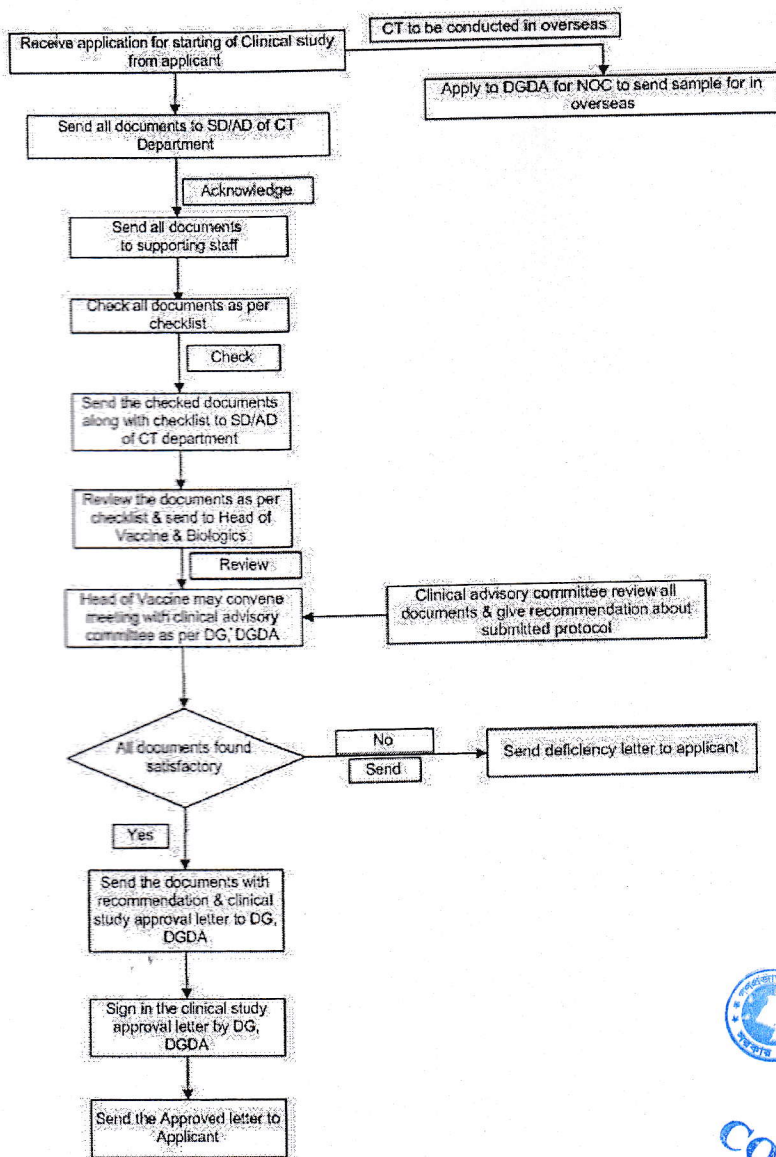

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Annexure – 2						
	FORM Title: Flowchart for the registration procedure for introduced vaccine and biological products manufactured in Bangladesh (Locally developed product by using Master seed)					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-013/F02-01	01	DEC' 21	DEC' 26		09.11.21	03 of 06

Permission to start of clinical study.



Tentative time need to execute for Approval letter issuance is maximum 45 days. Calculation of tentative time depends on as per submission of applicant's consecutive deficient documents.





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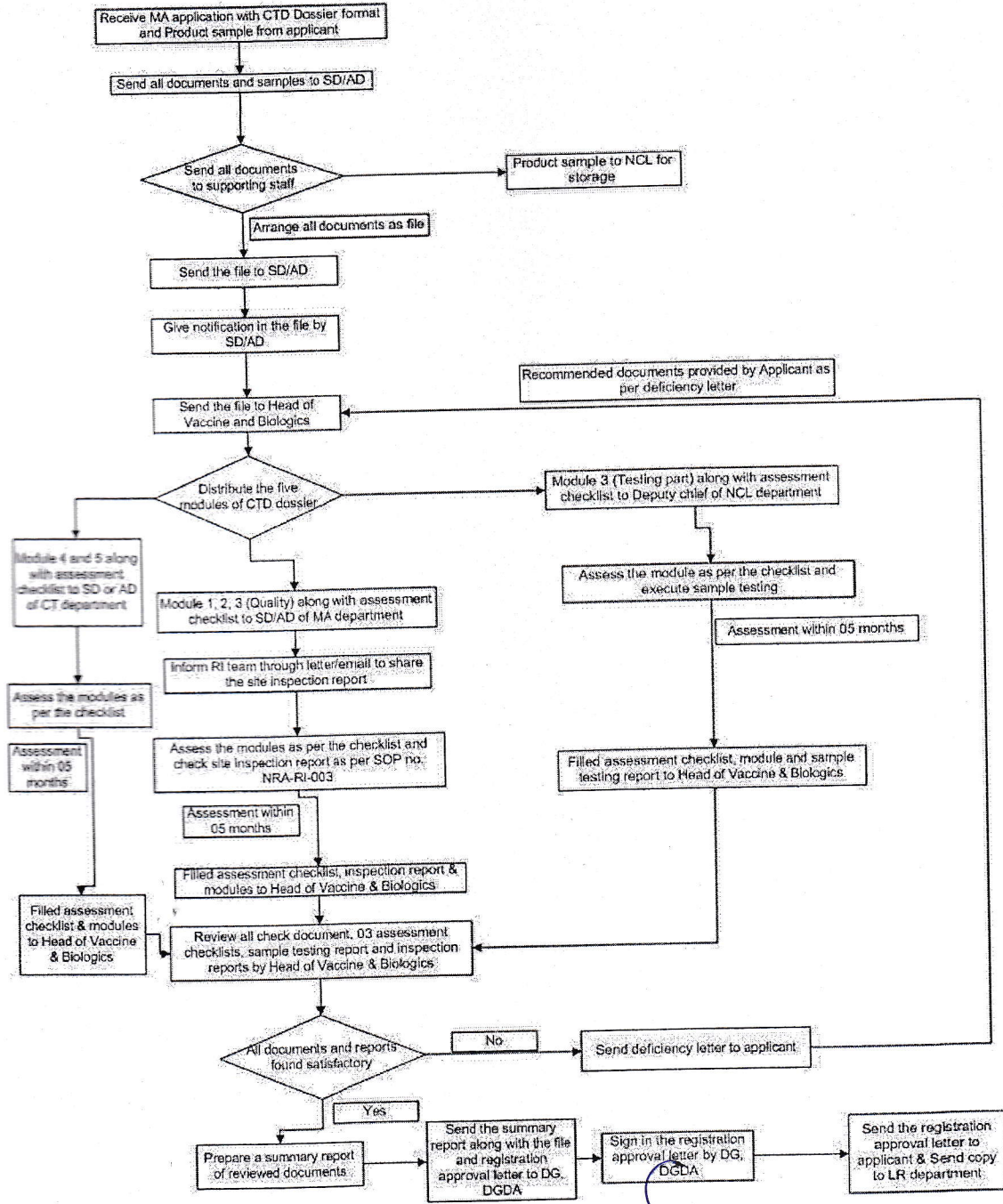
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Annexure - 2

	FORM Title: Flowchart for the registration procedure for introduced vaccine and biological products manufactured in Bangladesh (Locally developed product by using Master seed)					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-013/F02-01	01	DEC' 21	DEC' 26		09.11.21	04 of 06

Registration procedure for introduced vaccine using indigenous or locally developed bulk






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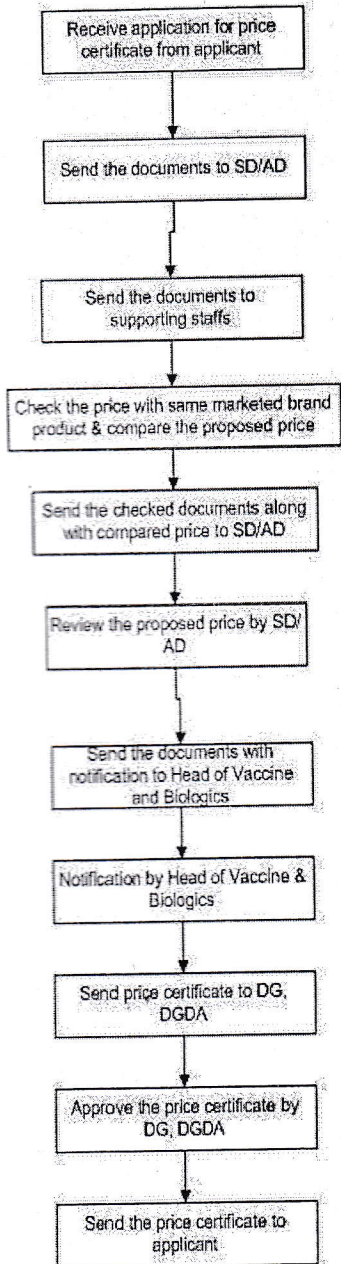
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Annexure - 2


	FORM Title: Flowchart for the registration procedure for introduced vaccine and biological products manufactured in Bangladesh (Locally developed product by using Master seed)					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-013/F02-01	01	DEC' 21	DEC' 26		09.11.21	05 of 06

Price certificate Issuance




DIRECTORATE GENERAL OF DRUG ADMINISTRATION (DGDA)
MINISTRY OF HEALTH AND FAMILY WELFARE
BANGLADESH




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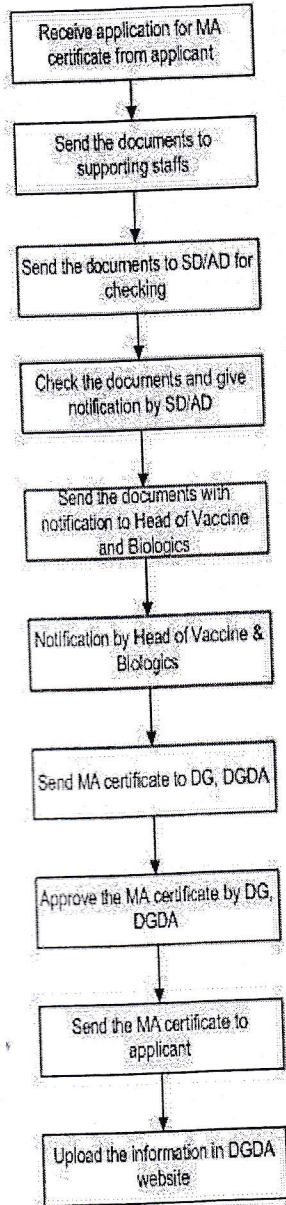
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Annexure - 2

	FORM Title: Flowchart for the registration procedure for introduced vaccine and biological products manufactured in Bangladesh (Locally developed product by using Master seed)					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-013/F02-01	01	DEC' 21	DEC' 26		09.11.21	06 of 06

MA certificate issuance



Tentative time need to execute up to MA certificate issuance is maximum 06 months. Calculation of tentative time depends on as per submission of applicant's consecutive deficient documents.






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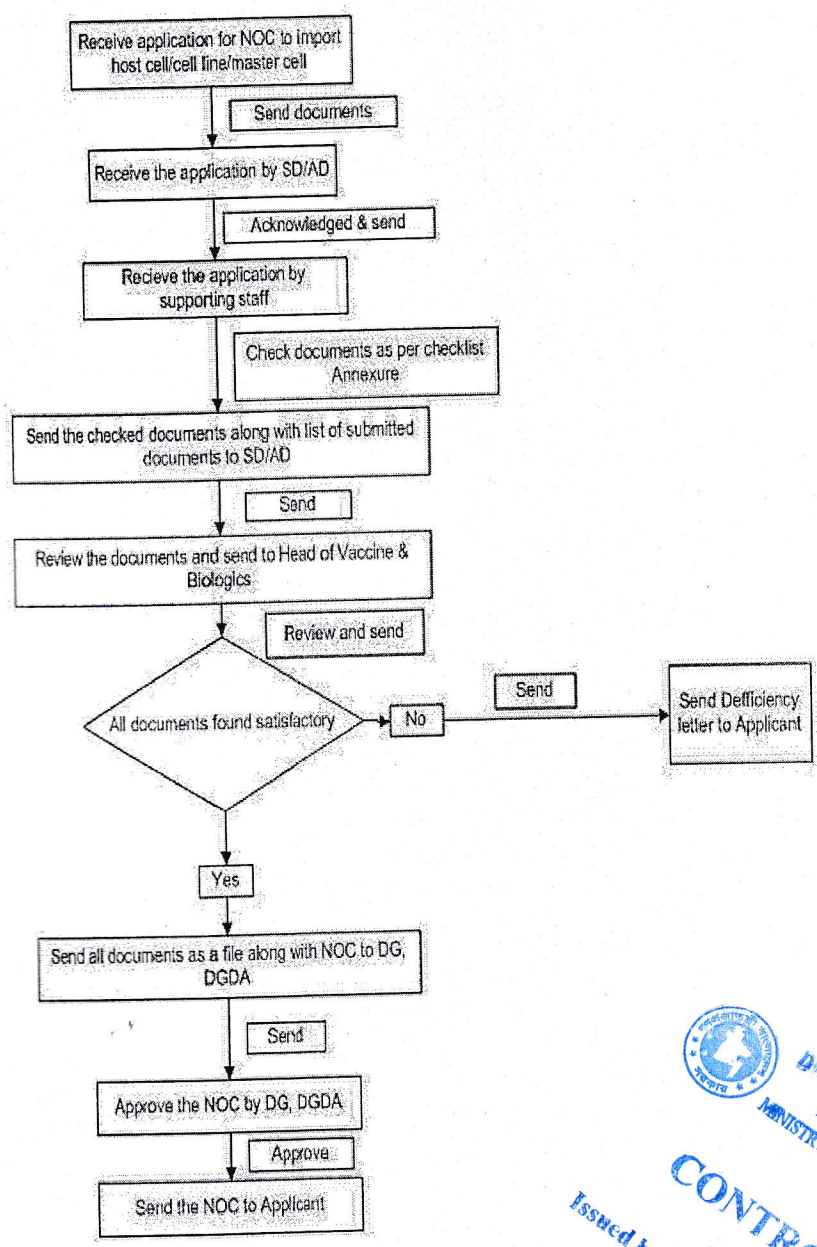
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MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

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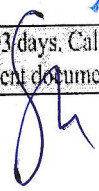
Annexure - 3

	FORM Title: Flowchart for the registration procedure for unimported or new vaccine and biological products in Bangladesh (Locally developed product by using Master seed)					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-013/F03-01	01	DEC' 21	DEC' 26		09.11.21	01 of 07

NOC to import host cell/cell line/master cell






Tentative time need to execute for NOC or permission letter issuance is maximum 03 days. Calculation of tentative time depends on as per submission of applicant's consecutive deficient documents.


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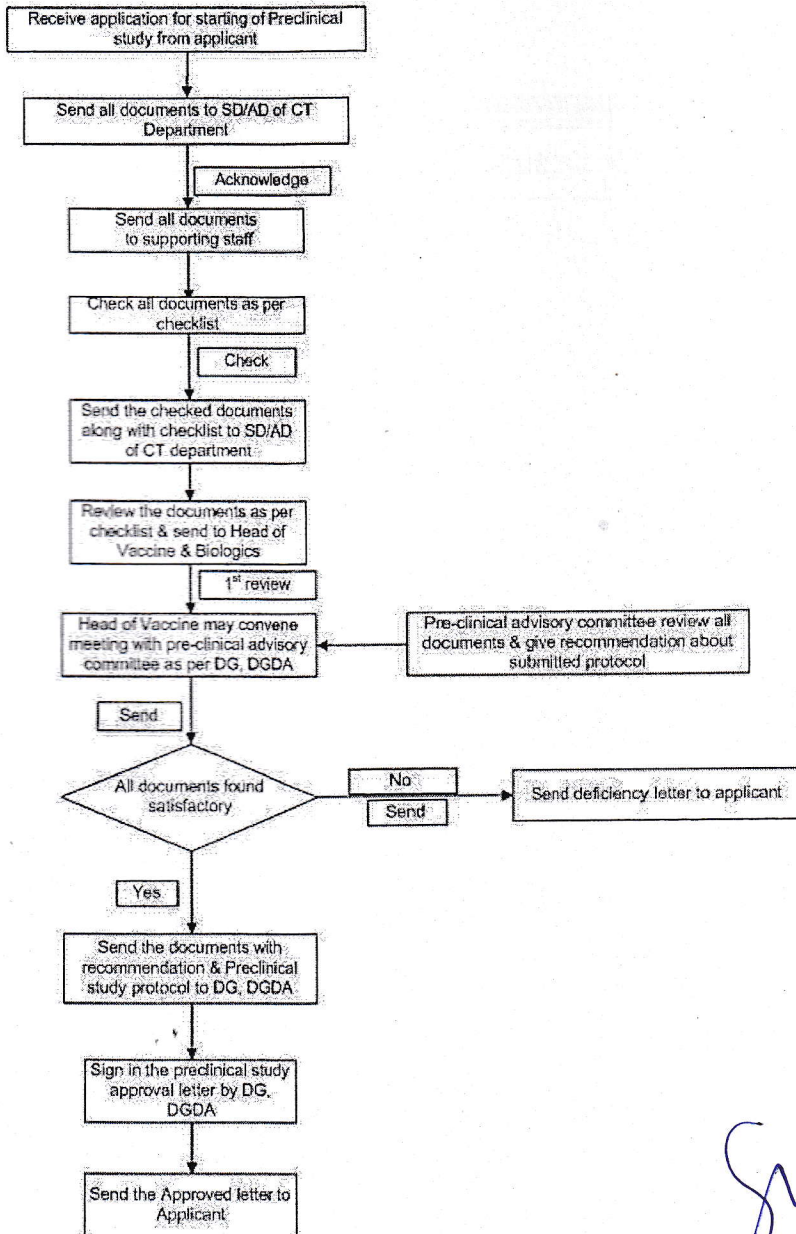
DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

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Annexure – 3

	FORM Title: Flowchart for the registration procedure for un-introduced or new vaccine and biological products in Bangladesh (Locally developed product by using Master seed)					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-013/F03-01	01	DEC' 21	DEC' 26		09.11.21	02 of 07

NOC to start of preclinical study






Tentative time need to execute for Approval letter issuance is maximum 45 days. Calculation of tentative time depends on as per submission of applicant's consecutive deficient documents.

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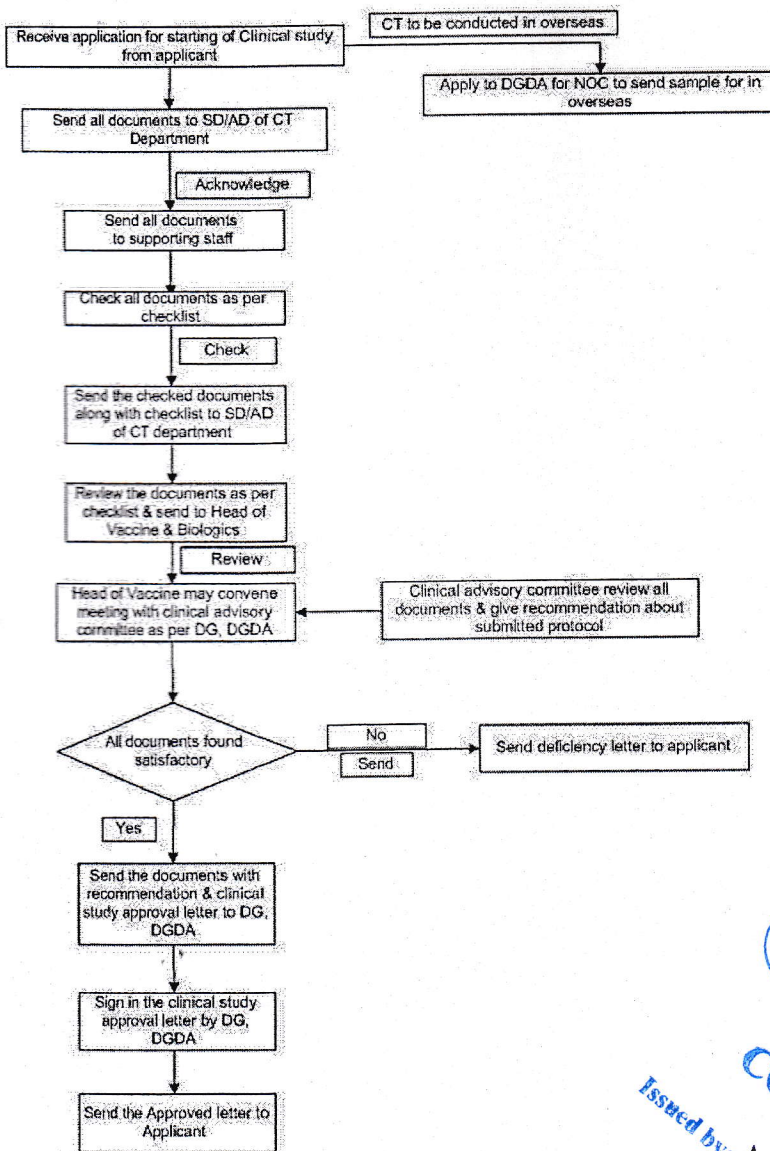
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MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

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	FORM Title: Flowchart for the registration procedure for un-introduced or new vaccine and biological products in Bangladesh (Locally developed product by using Master seed)					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-013/F03-01	01	DEC' 21	DEC' 26		09.11.21	03 of 07

Permission to start of clinical study






Tentative time need to execute for Approval letter issuance is maximum 45 days. Calculation of tentative time depends on as per submission of applicant's consecutive deficient documents

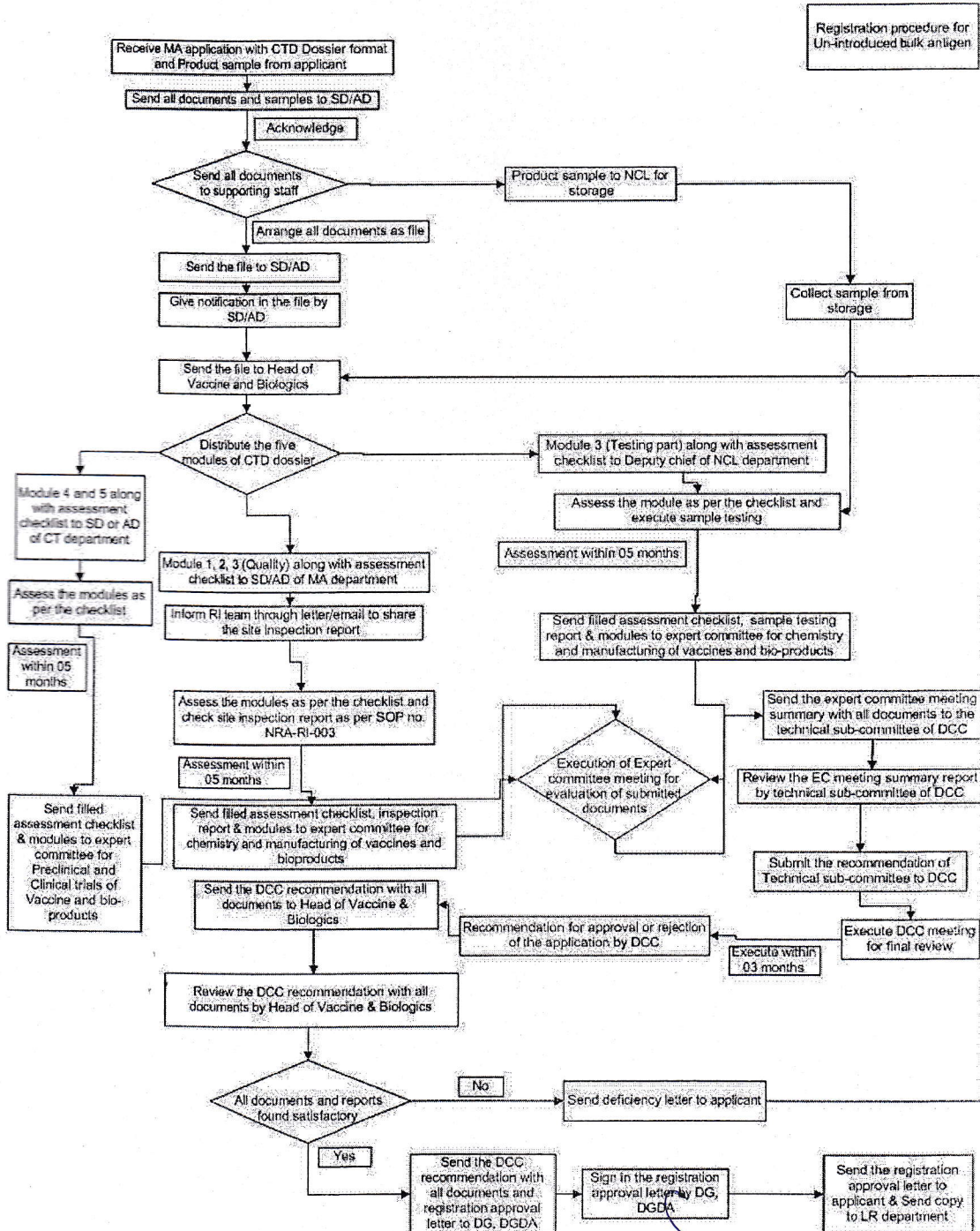

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MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

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Annexure – 3

	FORM Title: Flowchart for the registration procedure for un-introduced or new vaccine and biological products in Bangladesh (Locally developed product by using Master seed)						
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.	
NRA-MA-013/F03-01	01	DEC' 21	DEC' 26		09.11.21	04 of 07	



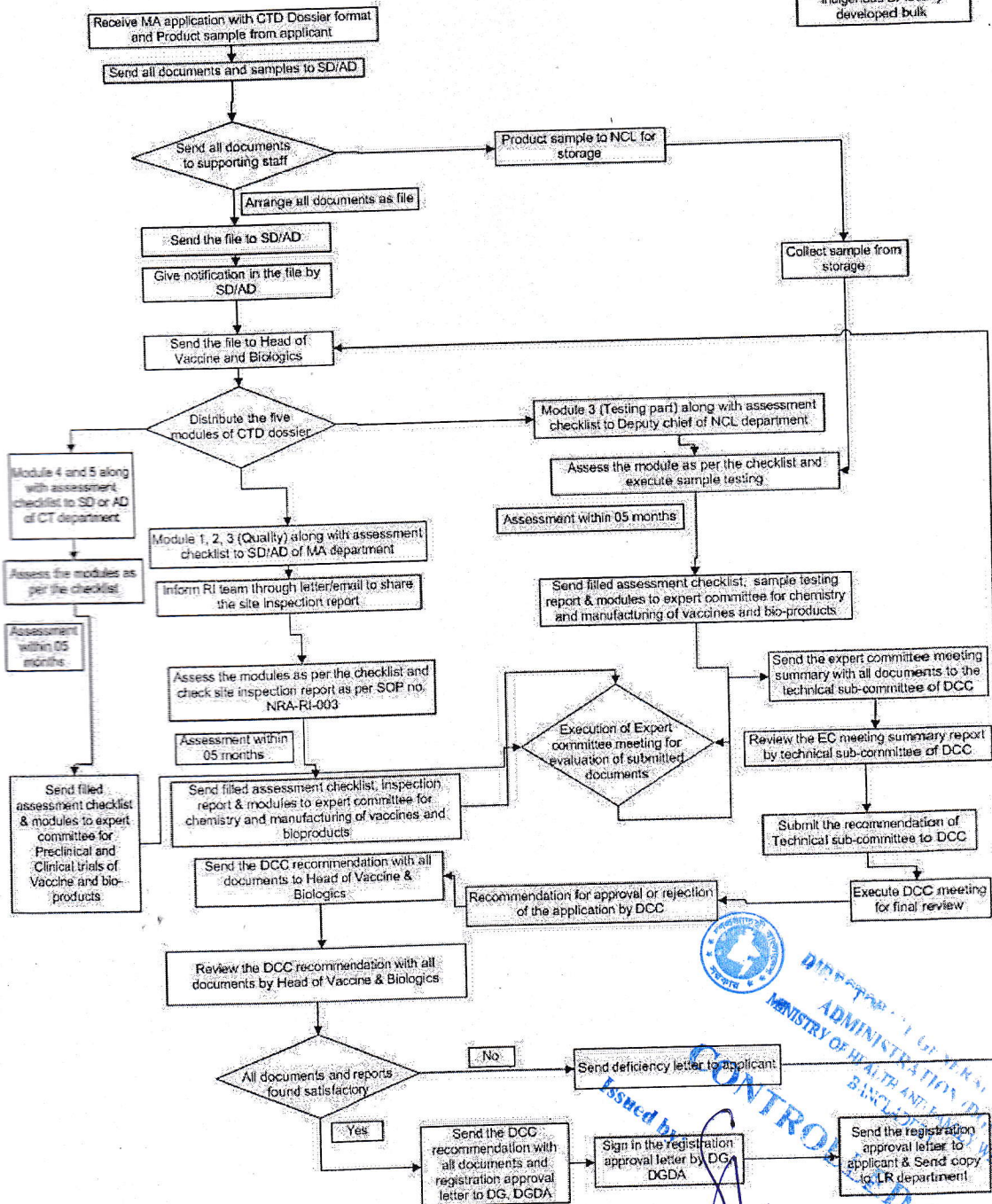
DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

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Annexure - 3

	FORM Title: Flowchart for the registration procedure for unintroduced or new vaccine and biological products in Bangladesh (Locally developed product by using Master seed)					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-013/F03-01	01	DEC' 21	DEC' 26		09.11.21	05 of 07

Registration procedure for Unintroduced vaccine using indigenous or locally developed bulk






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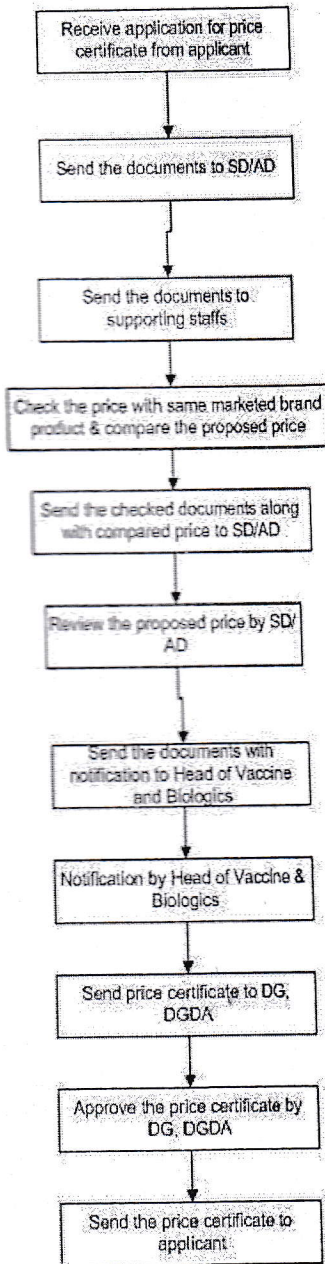

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Annexure - 3

	FORM Title: Flowchart for the registration procedure for un-introduced or new vaccine and biological products in Bangladesh (Locally developed product by using Master seed)					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-013/F03-01	01	DEC' 21	DEC' 26		09.11.21	06 of 07




Price certificate Issuance

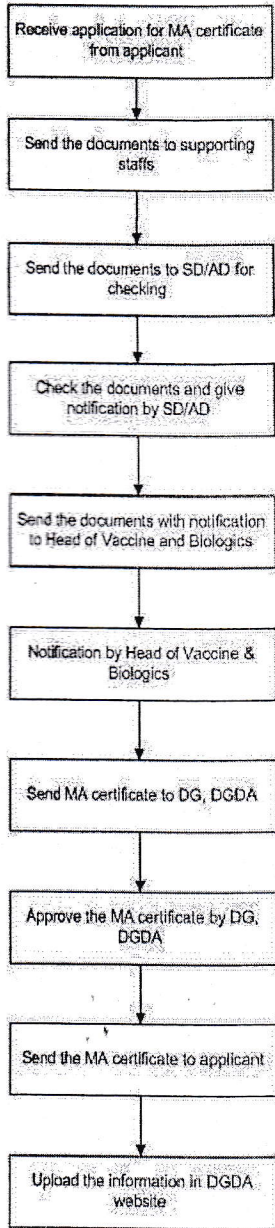
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Annexure – 3

	FORM Title: Flowchart for the registration procedure for un-introduced or new vaccine and biological products in Bangladesh (Locally developed product by using Master seed)					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-013/F03-01	01	DEC' 21	DEC' 26		09.11.21	07 of 07

MA certificate issuance






Tentative time need to execute up to MA certificate issuance is maximum 09 months. Calculation of tentative time depends on as per submission of applicant's consecutive deficient documents.


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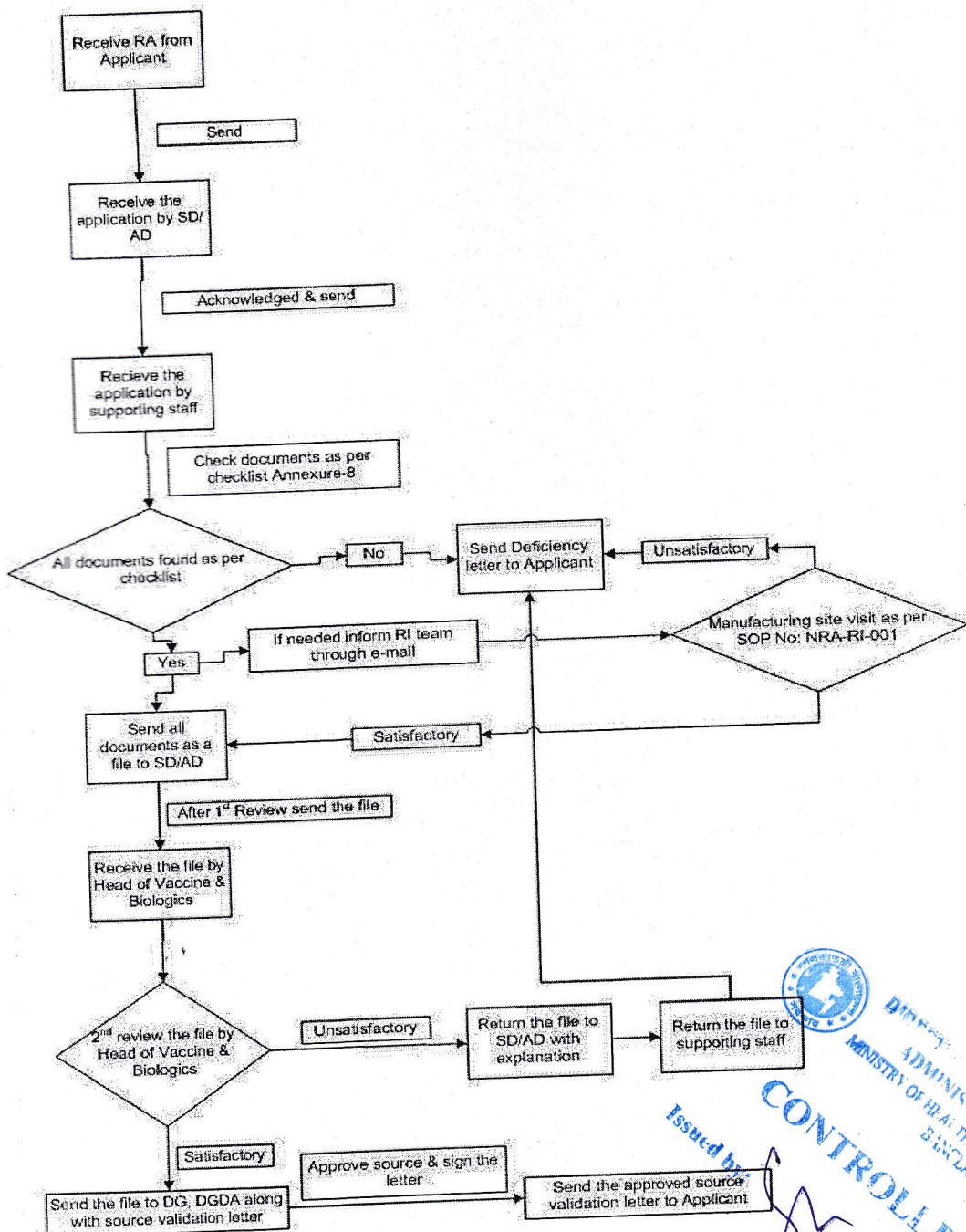
DIRECTORATE GENERAL OF DRUG ADMINISTRATION MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

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Annexure - 4


	FORM Title: Flowchart for the Un-introduced or new vaccine and biological products in Bangladesh (Locally manufactured product by using imported bulk)					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-013/F04-01	01	DEC' 21	DEC' 26		09.11.21	01 of 04

Source Validation



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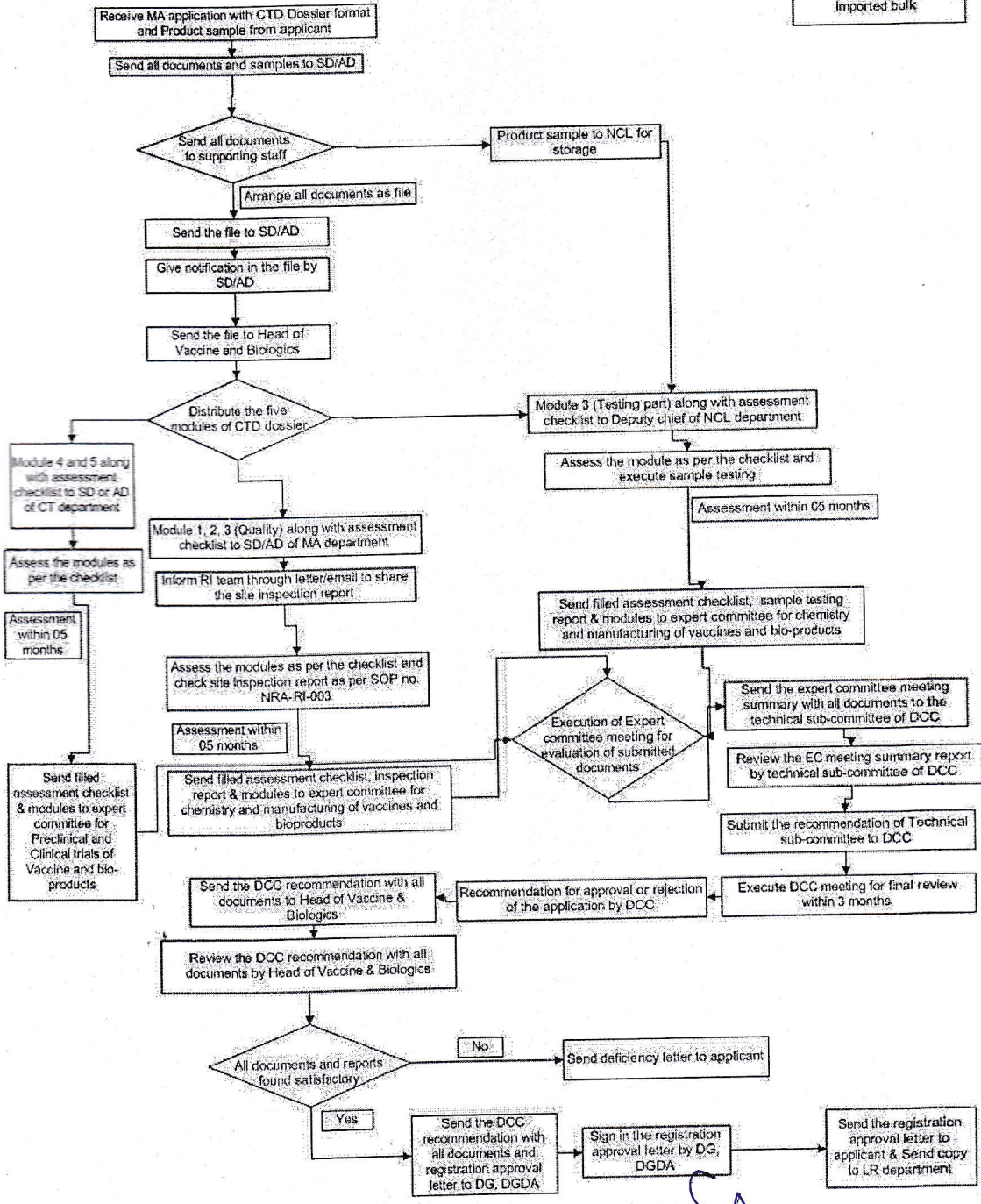


DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

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Annexure - 4						
	FORM Title: Flowchart for the Un-introduced or new vaccine and biological products in Bangladesh (Locally manufactured product by using imported bulk)					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-013/F04-01	01	DEC' 21	DEC' 26		09.11.21	02 of 04




Registration procedure for
Unintroduced vaccine using
imported bulk



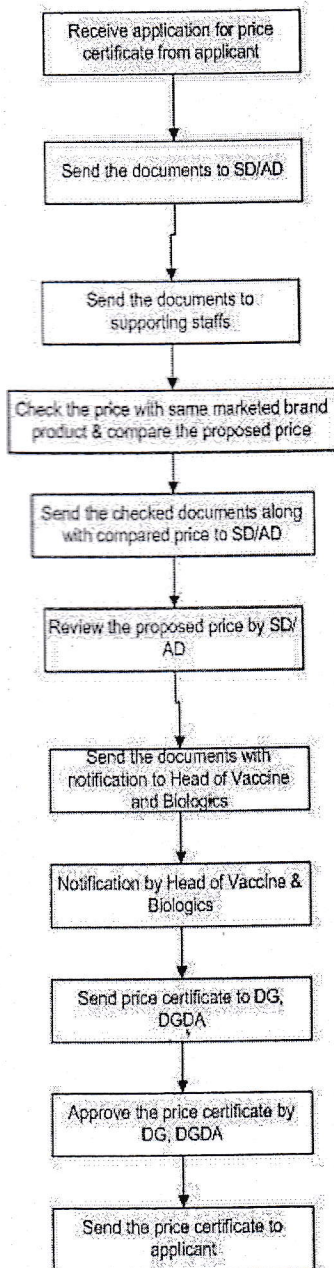
DIRECTORATE GENERAL OF DRUG ADMINISTRATION
MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

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Annexure - 4

	FORM Title: Flowchart for the Un-introduced or new vaccine and biological products in Bangladesh (Locally manufactured product by using imported bulk)					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-013/F04-01	01	DEC' 21	DEC' 26		09.11.21	03 of 04




Price certificate Issuance



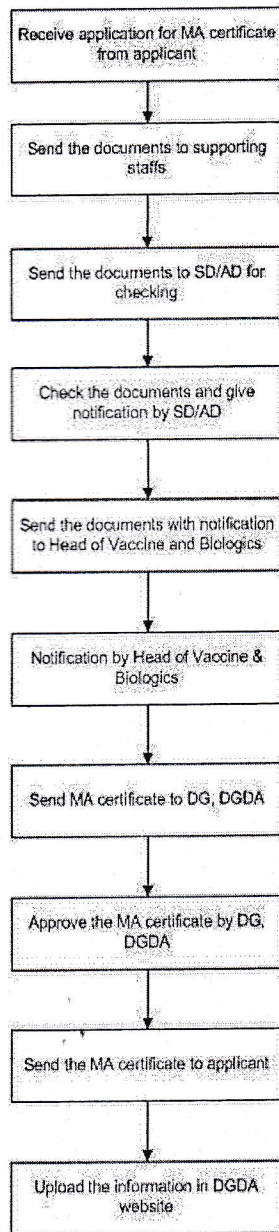
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Annexure – 4

	FORM Title: Flowchart for the Un-introduced or new vaccine and biological products in Bangladesh (Locally manufactured product by using imported bulk)					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-013/F04-01	01	DEC' 21	DEC' 26		09.11.21	04 of 04

MA certificate issuance



Tentative time need to execute up to MA certificate issuance is maximum 09 months. Calculation of tentative time depends on as per submission of applicant's consecutive deficient documents.


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MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

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Annexure - 5

		FORM Title: Flowchart for the registration procedure for introduced vaccine in Bangladesh (For imported finished product)				
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-013/F05-01	01	DEC' 21	DEC' 26		09.11.21	01 of 02

Receive MA application with COPP (1 of 7 reference developed countries or EMA according to DCC & Drug Policy) and product sample from applicant

Send all documents and samples to SD/AD

Send all documents to supporting staff

Arrange all documents as file

Send the file to SD/AD

Give notification in the file by SD/AD

Send the file to Head of Vaccine and Biologics

Check vaccine storage inspection report

Assess documents and check site inspection report as per SOP no. NRA-RI-003

Assessment within 05 months

Filled assessment checklist and inspection report to Head of Vaccine & Biologics

Review all check document and inspection reports by Head of Vaccine & Biologics

All documents and reports found satisfactory

No → Send deficiency letter to applicant

Yes

Prepare a summary report of reviewed documents

Send the summary report along with the file and registration approval letter to DG, DGDA




Sign in the registration approval letter by DG, DGDA

Send the registration approval letter to applicant & Send copy to LR department

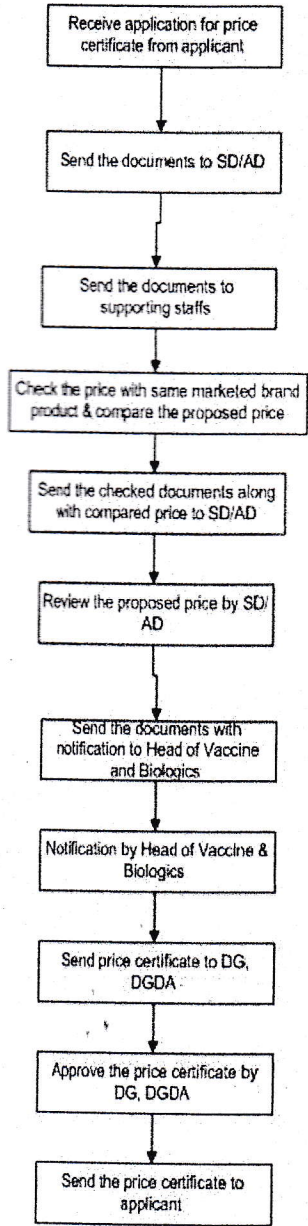
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MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH**


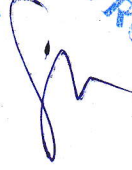
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Annexure - 5						
	FORM Title: Flowchart for the registration procedure for introduced vaccine in Bangladesh (For imported finished product)					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-013/F05-01	01	DEC' 21	DEC' 26		09.11.21	02 of 02

Price certificate issuance



Tentative time need to execute up to Price certificate issuance is maximum 06 months. Calculation of tentative time depends on as per submission of applicant's consecutive deficient documents.


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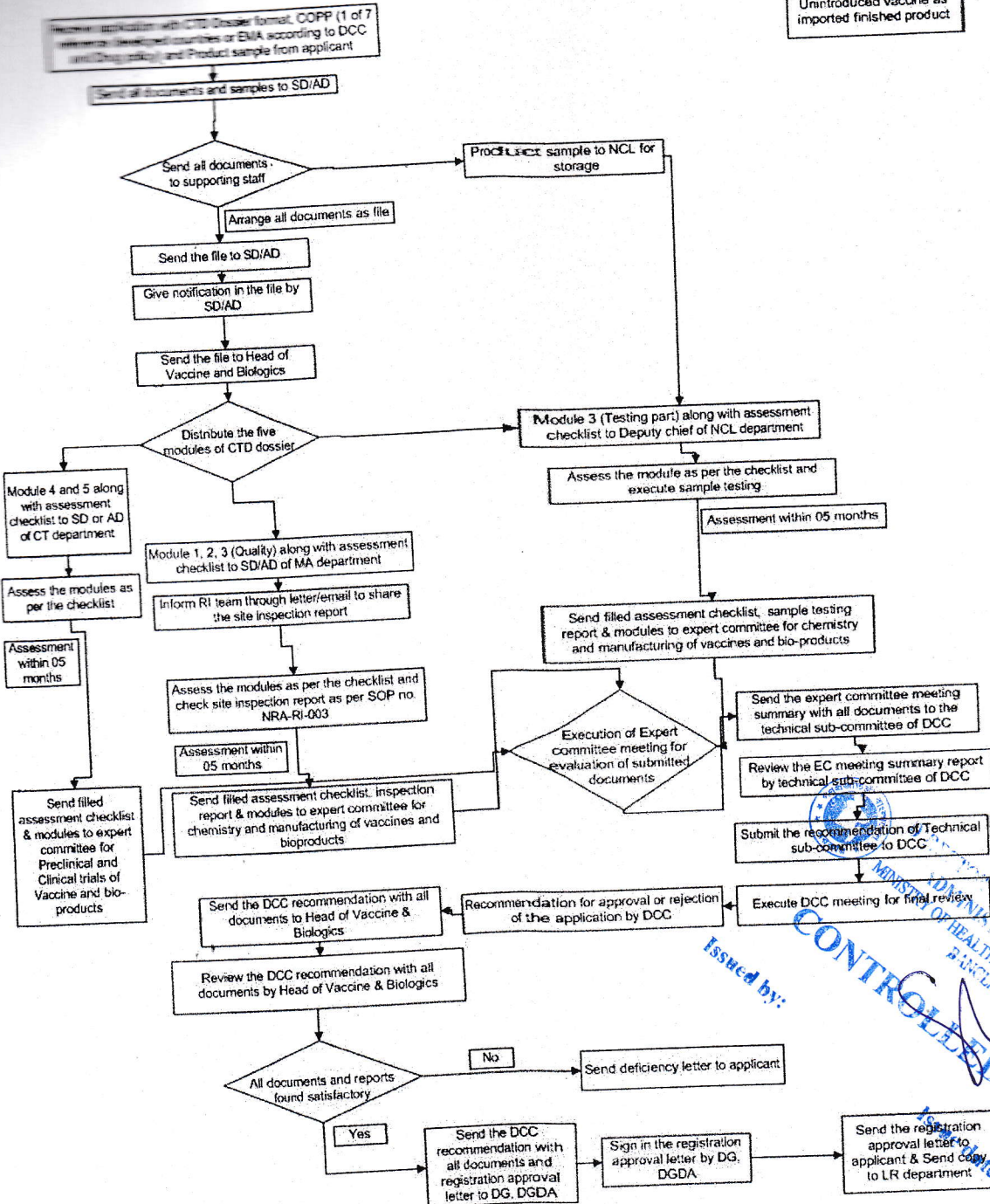
DIRECTORATE GENERAL OF DRUG ADMINISTRATION MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

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Annexure - 6

	FORM Title: Flowchart for the registration procedure for Unintroduced or new vaccine in Bangladesh (For imported finished product)	
Form No.	Version No.	Effective Date
01	01	DEC '21
Review Date	Authorized by	Date
DEC '26		09.11.21
		Page No.
		01 of 02

Registration procedure for Unintroduced vaccine as imported finished product



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 MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

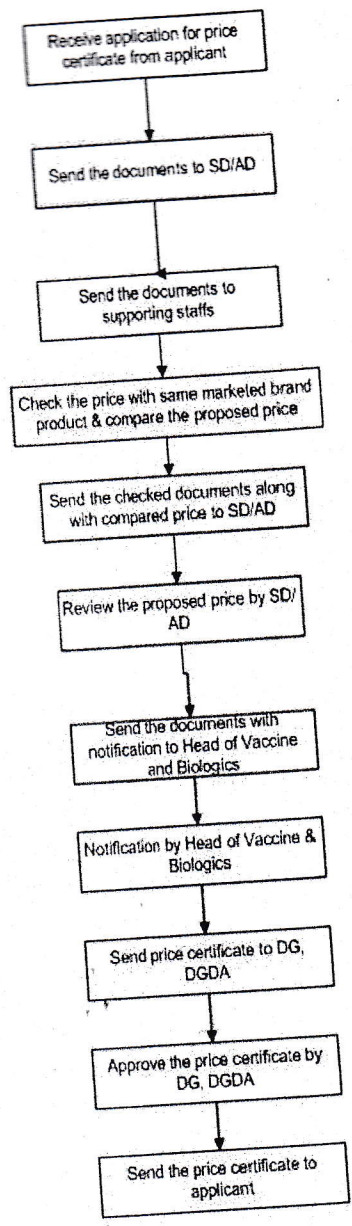
10 NOV 2021

DIRECTORATE GENERAL OF DRUG ADMINISTRATION
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 in Bangladesh (For imported unfinished product)					
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-013/F06-01	01	DEC' 21	DEC' 26		09.11.21	02 of 02

Price certificate Issuance



Tentative time need to execute up to Price certificate issuance is maximum 09 months. 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
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 Issue date:

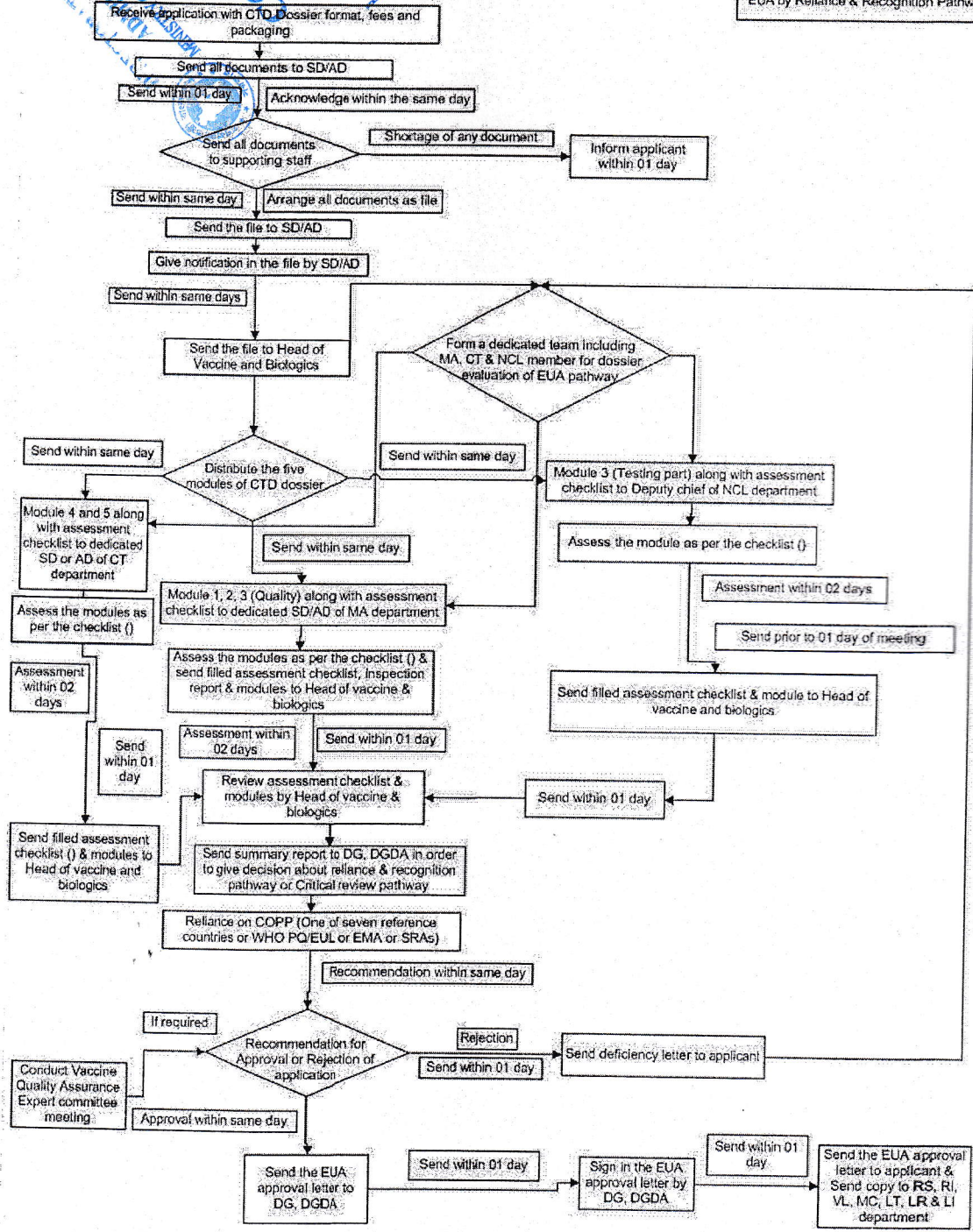
DIRECTORATE GENERAL OF DRUG ADMINISTRATION MINISTRY OF HEALTH AND FAMILY WELFARE, BANGLADESH

Authorized Personnel Only

Annexure – 16

FORM Title: Flowchart for Emergency Use Authorization (EUA) of vaccine and biological products in Bangladesh						
Form No.	Version No.	Effective Date	Review Date	Authorized by	Date	Page No.
NRA-MA-013/F16-01	01	DEC' 21	DEC' 26	<i>[Signature]</i>	09.11.21	01 of 03



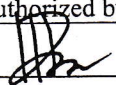
EUA by Reliance & Recognition Pathway



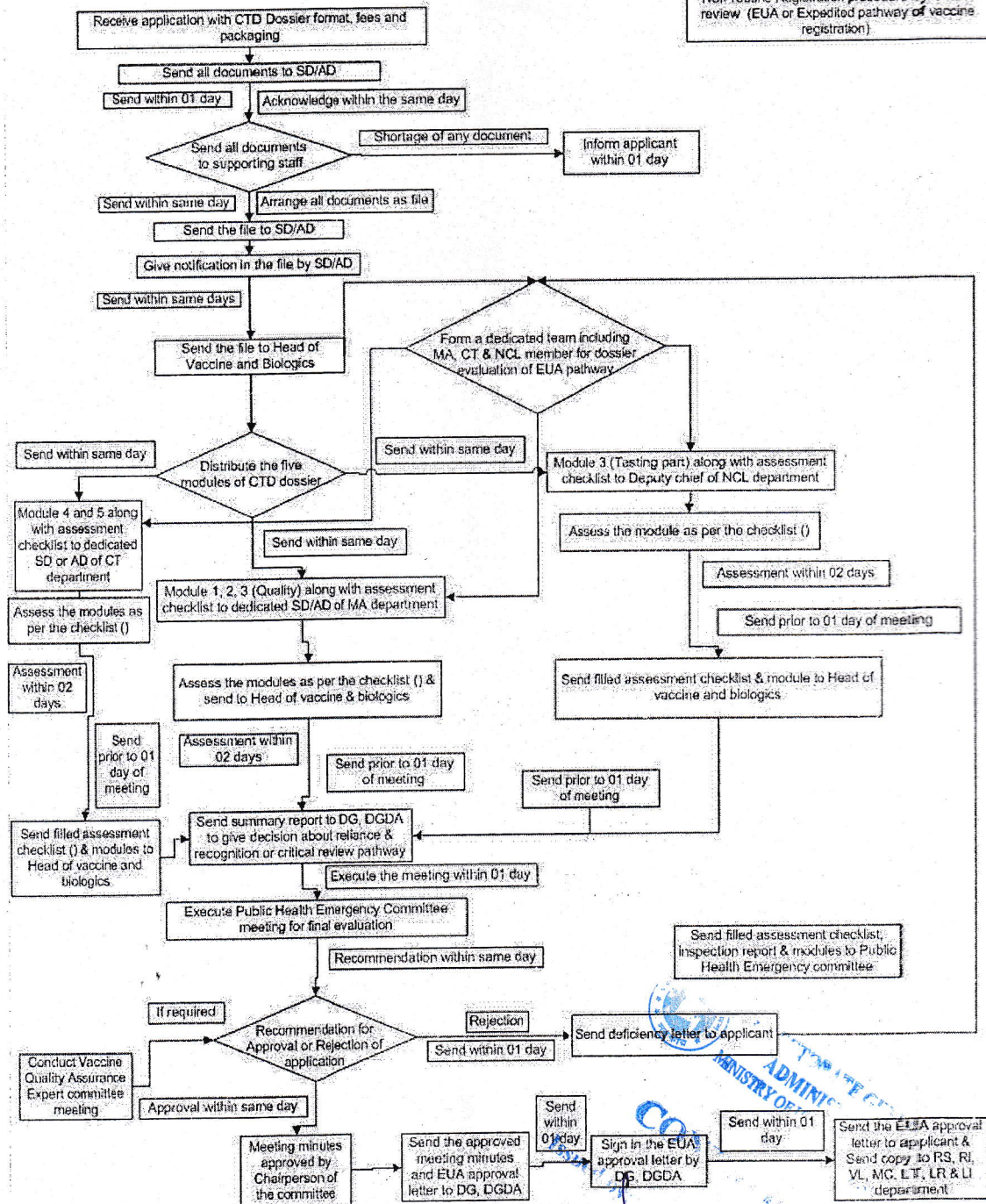
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NRA-MA-013/F16-01	01	DEC' 21	DEC' 26		09.11.21	02 of 03

Non-routine Registration procedure by Critical review (EUA or Expedited pathway of vaccine registration)



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

Issue date: **COPY**

