Appendix 3, Part C

Notification of outcomes of national registration procedure by the NRA

Product and application details as completed in Parts A and B above apply.

Please complete either section A or section B below:

☐ **Section A**

Registration has been granted under the terms of the Procedure, and the above-mentioned product ("the Product") is identified as follows in the national medicines register:

Name of the Product: _____

National registration number: _____

Date of registration (dd/mm/yyyy): _____

Non-regulatory time (days): _____

Product details (if different from those specified in Parts A and B):

Product details for pharmaceutical products:

API(s) (INN): _____

Dosage form and strength: _____

Packaging: _____

Manufacturing site(s), including block(s)/unit(s) if appropriate: _____

_____

Product details for vaccines:

Name of vaccine: _____

Composition: _____

Packaging: _____

Manufacturing site(s), including block(s)/unit(s) if appropriate: _____

_____

Registration holder (if different from the Applicant as specified in Parts A and B):

Name of entity: _____

Street: _____

City and country: _____

Email: _____

Telephone: _____

Are the national registration conclusions different from prequalification outcomes?[7] _____ (yes/no)

If you answered yes to the above question, please specify:

Deviation	Reason

Please specify whether registration is subject to specific commitments, the registration is provisional or conditional, use of the Product is limited by specific prescribing restrictions, or additional clinical trials or additional data are required:

_____

☐ **Section B**

Please complete as appropriate:

☐ The application for registration of the Product was rejected for the following reasons: _____

☐ The collaborative procedure was discontinued for this application for the following reasons: _____

For the NRA

Signature: _____

Name: _____

Title: _____

Place: _____

Date (dd/mm/yyyy): _____

[7] This refers to deviations in indications, contraindications, posology (dosing), special warnings and precautions for use, adverse drug reactions, storage conditions and shelf life. For pharmaceutical products differences in brand name, name of applicant/PQ holder, format of product information, level of detail of product information, labelling of internal and external packaging and language of product information are not considered to be a deviation from the PQ conclusions.