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 unless otherwise indicated below.

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 name: _____

Product code(s): _____

Regulatory version: _____

Manufacturer: _____

Manufacturing site(s): _____

Packaging: _____

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

Name of entity: _____

Street: _____

City and country: _____

Telephone number: _____ (please include codes)

Email: _____

Are the national registration conclusions different from the prequalification outcomes?[1]

☐ Yes ☐ No

[1] This refers to deviations in indications, contraindications, intended use, special warnings and precautions for use, storage conditions and shelf-life.

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 restrictions, or additional 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 Procedure was discontinued for this application for the following reasons:

_____

_____

_____

For the NRA

Signature: _____

Name: _____

Title: _____

Place: _____

Date (dd/mm/yyyy): _____