

Appendix 9

Notification of an outcome of the national registration provided by the participating manufacturer to the World Health Organization

Details of pharmaceutical manufacturer using the Procedure¹

Manufacturer: . _____

Country: . _____

Address: . _____

Focal point: . _____

Telephone number (please include codes): . _____

Email: . _____

Details of pharmaceutical product or vaccine (the Product) subject to the Procedure

Name of the Product: . _____

Active pharmaceutical ingredient (s): . _____

Strength: . _____

Dosage form: . _____

Course of the Procedure

Country: . _____

Regulatory authority: . _____

Date of submission of the application: . _____

Date of acceptance of the application (if different from submission date): . _____

Date of issuance of a decision: . _____

Length of process interruption/clock-stop (if applicable):² . _____

¹ Collaborative procedure in assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities – facilitated by WHO.

² Time provided by NRA to the applicant to complete data or respond to regulatory questions.

Decision on registration

Granted, rejected, withdrawn: . _____

Registration number (if applicable): . _____

Registration granted in line with the reference SRA decision or with deviations, please comment: . _____

Compliance with the Procedure, other observations and recommendations

In the course of the Procedure the following deviations were observed and recorded: . _____

Any other observations and recommendations: . _____

For the manufacturer

Signature: _____

Name: . _____

Title: . _____

Place and date: . _____