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: Click here to enter text. __________________________
Country: Click here to enter text. __________________________
Address: Click here to enter text. __________________________
Focal point: Click here to enter text. __________________________
Telephone number (please include codes): Click here to enter text. ___________
Email: Click here to enter text. __________________________

Details of pharmaceutical product or vaccine (the Product) subject to the Procedure
Name of the Product: Click here to enter text. __________________________
Active pharmaceutical ingredient (s): Click here to enter text. ___________
Strength: Click here to enter text. __________________________
Dosage form: Click here to enter text. __________________________

Course of the Procedure
Country: Click here to enter text. __________________________
Regulatory authority: Click here to enter text. __________________________
Date of submission of the application: Click here to enter text. ___________
Date of acceptance of the application (if different from submission date): Click here to enter text. __________________________
Date of issuance of a decision: Click here to enter text. ___________
Length of process interruption/clock-stop (if applicable):² Click here to enter text. __________________________

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Granted, rejected, withdrawn: Click here to enter text. ______________________
Registration number (if applicable): Click here to enter text. ________________
Registration granted in line with the reference SRA decision or with deviations, please comment: Click here to enter text. ______________________

Compliance with the Procedure, other observations and recommendations

In the course of the Procedure the following deviations were observed and recorded: Click here to enter text. ______________________
Any other observations and recommendations: Click here to enter text. ______

For the manufacturer

Signature:
Name: Click here to enter text. ______________________
Title: Click here to enter text. ______________________
Place and date: Click here to enter text. ______________________