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 Procedure[1]

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Granted, rejected, withdrawn: .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: . _____