Appendix 4

Report on post-registration actions in respect of a product registered under the Procedure

☐ Variation of the national registration resulting in the national registration conditions being inconsistent with the WHO/PQT prequalification conclusions

☐ Deregistration or suspension of the registration of the product

Product details:

Product name in national system: _____ ("the Product")

National registration number: _____

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

WHO prequalification details:

WHO PQ reference number: _____

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

WHO PQ holder: _____

☐ The national variation procedure has resulted in the nationally-registered Product being no longer the same[1] as the WHO-prequalified product.

Deviation	Reason

[1] Within the context of this Procedure, the same pharmaceutical product/same vaccine is characterized by the same product dossier; the same manufacturing chain, processes and control of materials and finished product, and in the case of vaccines also by the same batch release scheme; the same active ingredient and finished product specifications; as well as the same essential elements of product information for pharmaceutical products, and, in the case of vaccines, by the same product information, packaging presentation and labelling.

☐ The variation notified to the NRA by WHO/PQT has not been followed by a variation of the nationally-registered Product and, as a consequence, the nationally-registered product is no longer the same[1] as the WHO-prequalified product.

Deviation	Reason

☐ The Product has been deregistered or the registration of the Product has been suspended.

Deregistration: _____ (yes/no)

suspension of registration: _____ (yes/no)

Effective date: ____ /____ /____ (dd/mm/yyyy)

Reasons:

_____

_____

_____

_____

For the NRA

Signature: _____

Name: _____

Title: _____

Place: _____

Date (dd/mm/yyyy): _____