Appendix 4

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

☐ Change of the national registration resulting in the national registration conditions being inconsistent with the WHO prequalification conclusions

☐ Deregistration or suspension of the registration of the product

☐ Field Safety Corrective Action (FSCA) issued on 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):

Name of WHO PQ holder:

The national changes procedure has resulted in the nationally registered Product being no longer the same[31] as the WHO-prequalified product

Deviation	Reason

The changes notified to the NRA by WHO have not been followed by a change to the nationally registered Product and, as a consequence, the nationally registered Product is no longer the same[32] as the WHO-prequalified product

[31] Within the context of this Procedure, the same in vitro diagnostic is characterized by the same name (including proprietary name), same information, same design with comparable components from the same suppliers, same specifications, same regulatory version code, same site of manufacturer and quality management system, same data on quality and performance, same intended use, same labelling and packaging, and same instructions for use.

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):

[32] Within the context of this Procedure, the same in vitro diagnostic is characterized by the same name (including proprietary name), same information, same design with comparable components from the same suppliers, same specifications, same regulatory version code, same site of manufacturer and quality management system, same data on quality and performance, same intended use, same labelling and packaging, and same instructions for use.