Agência Nacional de Vigilância Sanitária

World Health Organization

August 31 2012.

STATEMENT OF COLLABORATION ARRANGEMENTS BETWEEN ANVISA AND THE QUALITY, SAFETY AND STANDARDS UNIT OF THE DEPARTMENT OF IMMUNIZATION, VACCINES AND BIOLOGICALS (WHO/FWC/IVB/QSS) OF THE WORLD HEALTH ORGANIZATION (WHO) IN TERMS OF THE PREQUALIFICATION PROCESS OF VACCINES

The Brazilian Health Surveillance Agency – ANVISA – confirms that regulatory oversight is continuously and regularly performed on the licensed vaccines listed in the Annex 2. ANVISA based on the regulatory system and oversight of the vaccines, that is found functional and in compliance with WHO recommended functions (e.g.: Licensing, lot release policy, regulatory inspections, evaluation and authorization of clinical trials, access to laboratory - testing of vaccine samples; and control of adverse events following immunization and post marketing surveillance), and in correspondence with national and international regulatory documents which are in line with WHO recommendations.

Based on the current level of functionality, as for the vaccines referred in Annex 2, and under a confidentiality arrangement signed with WHO dated **August 27 2012**, ANVISA will provide to WHO/FWC/IVB/QSS information on:

- Testing the vaccine lots to be supplied to United Nations agencies. ☒
- Release of the vaccine lots to be supplied to United Nations agencies. ☒
- Provide feedback on findings during regulatory inspections. ☒
- Update on safety and efficacy data. ☒
- Notification of severe / serious / unexpected adverse events following immunization (AEFIs) or efficacy related issues with public health implications. Notification of new safety signals. Exchange of findings. ☒
- Variations to the marketing authorization / license that have been notified or approved. ☒
- Any significant quality issues identified. ☒
- Marketing authorization / license renewals or withdrawals. ☒
- Recalls or withdrawal of lots of vaccines. ☒

On the other hand, and under the same signed confidentiality arrangement, the Office of the Prequalification Programme Manager of WHO/FWC/IVB/QSS will provide ANVISA subject of this collaboration arrangement with the following:

- Information on any lot that fails the WHO independent testing;

- Any reported quality related defect or non-compliance of a vaccine in the field;
- Information on any lot subject of recall and market withdrawal;
- Notification of severe / serious / unexpected adverse events following immunization (AEFIs) or efficacy related issues with public health implications reported from the field. Notification of safety signals. Exchange of findings;
- Exchange of views and opinions on relevant regulatory and programmatic issues with impact on the prequalification of a vaccine;
- Maintain on-going dialogue and collaboration regarding ways to optimize the interaction between the WHO and ANVISA.
- Share WHO reports of site audits to Brazilian manufacturers of prequalified vaccines or those undergoing PQ process.

Agreed and accepted on behalf of the **ANVISA:**

<Signature>
Dirceu Brás Aparecido Barbano
Diretor Chairman

Agreed and accepted on behalf of **WHO/FWC/IVB:**

<Signature>
Dr. Jean-marie okwo-bele
Director

<Date> 15 oct 2012