

**AMENDMENT NO 1**

to

**MEMORANDUM OF UNDERSTANDING**

between

**FOOD AND DRUG ADMINISTRATION  
UNITED STATES OF AMERICA**

and

**THE PAN AMERICAN HEALTH ORGANIZATION,  
REGIONAL OFFICE OF THE WORLD HEALTH ORGANIZATION**

This Amendment No. 1 is entered into by and between the Food and Drug Administration of the United States of America (“FDA”) and Pan American Health Organization, Regional Office of the World Health Organization (“PAHO” or “PAHO/WHO”), referred to jointly as the “Parties.”

WHEREAS the Parties entered into a Memorandum of Understanding (“MOU”) for the Regulatory Exchange Platform – secure, effective 5 May 2016;

WHEREAS the national regulatory authorities (“Participating NRAs”) that developed the Medical Device Single Audit Program (“MDSAP”) and combined efforts with PAHO to develop the Regulatory Exchange Platform – secure (“REPs”) pursuant to the MOU, have requested PAHO to work with authorized Auditing Organizations (“AO”) in an effort to fully implement and sustain MDSAP;

WHEREAS PAHO, as part of its technical cooperation program, has agreed to the request to collaborate with the authorized AOs to facilitate the exchange of non-public information and reports by AOs through REPs, and to administer financial contributions from AOs to sustain the program;

NOW THEREFORE, FDA and PAHO agree to amend the MOU as follows:

- I. Add the following sub-clauses to “Section 3: Intentions of PAHO”:
  - j. Agree on a biennial budget with NRAs who participate in budget discussions that will support continued administration, maintenance, and improvements, if needed, to the REPs technical cooperation platform. The budget will include a line item for PAHO’s program support costs (“psc”).

- k. Annually review the status of the budget with NRAs who participate in budget discussions, making adjustments as agreed.
- l. Establish agreements and/or other arrangements with authorized AOs, as PAHO deems necessary, to (i) facilitate authorized AOs to exchange non-public information through REPs; and (ii) accept and administer financial contributions from authorized AOs in accordance with PAHO's regulations and rules.

II. Add the following sub-clauses to "Section 4: Intentions of FDA":

- f. Provide PAHO a list of AOs that have been authorized, updating the list when there are changes.
- g. If FDA determines that it has statutory or other authority,
  - 1. Agree on a biennial budget with PAHO that will support PAHO's continued administration, maintenance, and improvements, as needed, to the REPs technical cooperation platform. FDA acknowledges that the budget will include a line item that includes PAHO's program support costs ("psc").
  - 2. Annually review the status of the budget with PAHO, making adjustments if agreed by all parties.

III. Amend "Section 6: Reporting" by adding the following:

PAHO will prepare a consolidated annual financial report to be submitted to participating NRAs.

IV. Amend "Section 12: Effective Date, Modification, and Termination" by adding the following:

- d. In the event this MOU is terminated, PAHO and Participating NRAs will mutually agree on the disposition of any unused or unobligated financial contribution that PAHO may have received from AOs as part of the REPs program.

V. Amend "Section 10: Disclaimer" by adding the following at the end:

Notwithstanding any other provision of this document, if an NRA determines that it lacks statutory or other authority to participate in budget discussions, it will not participate in any budget discussions.

All other terms and conditions of the MOU, as originally signed, remain unchanged and in full force and effect.

IN WITNESS WHEREOF, the parties hereto have duly executed two copies of this Amendment No. 1 as of the date of last signature below.

FOR THE FOOD AND DRUG ADMINISTRATION  
UNITED STATES OF AMERICA

\_\_\_\_\_/s/\_\_\_\_\_  
Mark Abdo  
Associate Commissioner of Global  
Policy and Strategy

July 15, 2019

FOR THE PAN AMERICAN HEALTH ORGANIZATION,  
REGIONAL OFFICE OF THE WORLD HEALTH ORGANIZATION

\_\_\_\_\_/s/\_\_\_\_\_  
Dr. Carissa F. Etienne  
Director

July 30, 2019