Project Proposal

For consideration by the Steering Committee

(Please submit to the PANDRH Secretariat (PAHO): parf@paho.org)

Proposed title for the area/project	**Strengthening of regulatory capacity on medical devices in the Region of the Americas**
Proponent	Center for State Control of Medicines and Medical Equipment and Devices (**CECMED, Cuba), together** with the National Institute for Drug and Food Surveillance (**INVIMA, Colombia),** with the support of the Medicines and Health Technologies Unit of the Pan American Health Organization (PAHO), the Regional Advisor on Health Technologies, and the Regional Working Group on Medical Device Regulation.
Objective and rationale (with reference to one or more of the objectives of the PANDRH Strategic Development Plan)	**General Objective** Identify and strengthen regulatory capacity on medical devices in the Region by training professionals who work in the regulatory authorities and by mapping the regulatory situation in the Region in order to gradually expand the work, learning, and prospects of the Regional Working Group on Medical Devices to benefit in the 35 countries of the region. **Specific Objectives** • Review, update, and adjust the basic indicators with regional mapping of medical device regulation in the 35 countries of the Region (Regional Working Group + remaining countries) • Strengthen regional regulatory capacity on medical devices through two courses: 1) Basic course on regulation of medical devices (CECMED); and 2) Course on technological surveillance (INVIMA). **Rationale:** This project seeks, in a coordinated and strategic manner, to comply with Resolution WHA 67.20 on Regulatory system strengthening for medical products, in addition to focusing on WHO's prioritization of medical devices, which emphasizes regulatory oversight throughout the life cycle of medical devices—something that is asymmetrical in the 35 countries of our Region. As a result, it is important *to update the basic indicators and the results obtained through their application in the regional mapping* led by Uruguay in 2012 in twelve NRAs of the Americas, providing information on the 35 countries in the Region. In addition, this initiative focuses on *strengthening the capacity and technical assistance* that the regulatory authorities of the Region of the Americas need in order to increase their regulatory capacity. It is important to give special attention to fulfilling the agreements made in the meeting of the PANDRH Directing Council in which the need to implement the decisions of the VII Conference was expressed, the work

	being carried out on medical devices at the regional level was presented, and the importance of the results of the work done to strengthen regulatory capacity on this type of health technologies was expressed by the Members of the Steering Committee. This initiative underlines the importance that the NRAs of the Region attribute to medical device regulation and the strengthening of regulatory capacity. In light of the above, it is necessary to include these issues in PANDRH's discussions, in addition to the regional production of indicators to support the evaluation of capacity with regard to medical devices, so that the Region can make an important contribution to global discussions.[1] At the same time, taking into consideration the objectives of the Strategic Development Plan, this project falls within strategic objective IV, to "*promote the exchange of experiences and regulatory knowledge between NRAs within the Network and with NRAs outside PANDRH*" and is also justified by the need to strengthen the NRAs in order to improve access to quality health technologies and to strengthen health systems overall.[2] The existence of the PAHO/WHO Collaborating Center for the Regulation of Health Technologies in CECMED Cuba is one of the Region's strengths in terms of regulatory development for medical devices. The sharing of experiences among regulatory authorities of the Region of the Americas has become an increasingly important window for the exchange of information, knowledge, and experiences, helping to strengthen the regulatory capacity of NRAs in the Region. This initiative, coordinated by the two NRAs (INVIMA, Colombia; and CECMED, Cuba), the PAHO Regional Advisor on Health Technologies, and the Regional Working Group on Medical Device Regulation, will facilitate the generation and exchange of knowledge based on the challenges facing the Region with regard to medical devices. This is why the two authorities will bring together the best of their experience in medical device regulation in order to share it with the Region, based on the experience developed within the framework of the Regional Working Group on Medical Device Regulation and its secretariat, which provides advisory services. In Colombia, between 2010 and 2016, INVIMA has provided in-person training on post-marketing surveillance of medical devices to health professionals in the country's hospitals and clinics, health ministries, and importers and manufacturers, raising awareness among 7,560 professionals. A virtual education strategy was also implemented, and the "INVIMA Learning" platform was developed, based on e-learning and b-learning methodologies, with 426 people trained since 2014.

[1] Minutes of the Meeting of the PANDRH Steering Committee, Washington, D.C., 27-28 May 2015
[2] Strategic Development Plan 2014-2020 of the Pan American Network for Drug Regulatory Harmonization (PANDRH), p. 25

	CECMED's Medical Devices Office has almost 20 professionals working in the areas of conformity assessment and post-marketing surveillance, with sufficient competencies to deliver the content of the proposed course. This course is accredited by the National School of Public Health, as approved by government resolution. Between 2014 and 2016, in-person and virtual training has been provided to more than 100 specialists in Cuba, including those working for manufacturers, suppliers, and distributors of medical devices, as well as health institutions.
Scope (including points that should be addressed and opportunities for regulatory convergence)	Points for consideration: In May 2016 in Brasilia, during NRAs of referenece meeting, CECMED and INVIMA presented the proposed PANDRH regional project, focused on helping to strengthen the regulatory capacity of the countries of the Region, contributing all their expertise in medical device regulation. Accordingly, INVIMA and CECMED would promote the following, with the countries of the Region and with the support of the Regional Advisor on Health Technologies / Regional Working Group on Medical Device Regulation: 1) **Mapping of medical device regulation in the countries of the Region**: a. Updating of basic indicators b. Application of the indicators in the 35 countries of the Region 2) **Courses**: a. Basic course on regulation of medical devices—CECMED b. Technology surveillance—INVIMA CECMED, through its Medical Devices Office, offers the countries of the Region its function as PAHO/WHO Collaborating Center for medical device regulation, based on international experience, regional performance, and implementation in the Cuban system. INVIMA, through the Office of Medical Devices and Other Technologies, has structured a risk management model for health surveillance in recent years. It now wishes to share the National Technology Surveillance Program and the e-learning and b-learning system with the countries of the Region. **Specific Objective** **1. *Review, update, and adjust the basic Indicators with regional mapping of medical device regulation in the 35 Member States of PAHO (Regional Working Group + remaining countries)*** **Activity 1.1 Conduct mapping of medical device regulation in the Region**

	The measurement instrument will be implemented in the 35 countries of the Region, using the basic indicators developed in 2012 by the Ministry of Public Health of Uruguay to determine the state of regulation of medical devices in the countries of the Working Group. The following aspects will be evaluated as part of phase I: • Structure of regulation of medical devices in the country • Regulation of medical devices • Regulation of medical device companies/establishments • Organizational structure in the area of medical devices • Health risk communication • Incorporation of new technologies and procurement of strategic products and supplies The PAHO Regional Advisor on Health Technologies, in collaboration with the members of the Regional Working Group on Medical Device Regulation will be in charge of coordination and communication with the countries (Annex 1: Regulation of Medical Devices in the Countries of the Region). The representatives of each country will have one month to duly complete the form and send it to PAHO. The Regional Advisor on Health Technologies / Regional Working Group on Medical Device Regulation will consolidate the information for analysis, conclusions, and preparation of the final report. **Phase I:** • Update the current state of medical device regulation in the 16 member countries of the Working Group. **Phase II:** • Support regional efforts to generate and consolidate information by translating documents required for English-speaking countries. • Apply the instrument to generate information on medical device regulation in the remaining countries of the Region. • Establish mapping of medical device regulation in the entire Region. **Scope:** • Apply the advanced indicators in the 35 countries of the Region. • Determine the regulatory gaps with respect to medical devices in the Region in order to support international cooperation. Once the regional mapping of medical device regulation in all 35 countries of the Americas has been completed, the regulatory capacity of each country will be determined. This will make it possible to better focus the actions taken by the regional group to strengthen regulatory capacity in

response to the needs of each country. For its part, INVIMA could support the translation and adaptation of CECMED and INVIMA training content.

OBJECTIVE 2:

- ***Strengthen regional regulatory capacity on devices through two courses: Basic course on regulation of medical devices (CECMED); and Technology surveillance (INVIMA) (PRAIS community of practice)***

Activity 2.1 Support health education in the Region with Support of ICT

Structure of virtual training courses

A. Technology surveillance (INVIMA):

Scope of Virtual Phase I: 100 people from the 35 countries of the Region each semester for 12 weeks.

Study topics: Two (2) modules:

- **Technology Surveillance Module**: Competencies of INVIMA and general information on medical devices; components and operation of the Technology Surveillance Program in Colombia; forms of implementation and other topics of interest such as the reuse of medical devices.

- **Foreia Module:** Consists of three (3) thematic units aimed at presenting tools for the analysis and interpretation of adverse events and incidents associated with the use of medical devices, with interactive examples of applied cases using each reactive methodology studied.

Scope of Phase II (Week of in-person study): Internship in Colombia for regulatory authorities who have completed the virtual phase and who are among the top 10 students. INVIMA will cover the costs through national projects with stakeholders.

Topics of Study:

- Progress in the evaluation of efficacy and effectiveness of medical devices in Colombia
- Evaluation of effectiveness and licensing of medical devices
- Inspection, surveillance, and control of medical devices and in-vitro diagnostic reagents
- Post-marketing surveillance of Reagents of in-vitro diagnostic reagents
- Management of reported serious adverse events and incidents with medical devices
- Monitoring of safety alerts, recalls, and reports

	• Technical assistance and training: INVIMA VIRTUAL CLASSROOM learning modules • Web application of the National Technology Surveillance Program. Signaling methodology. B. **Structure of Course on Medical Device Regulation (CECMED)**: **Scope of Virtual Phase 1:** 100 people from the 35 countries of the Region each semester for 3 months. **Study topics: Three (3) modules:** • **Foundations of a regulatory program:** The history of medical device regulation will be presented, from its emergence through the stages of regional development. The differences between the regulation of medical devices and medicines will be explained, while also specifying fundamental concepts in the implementation of regulatory programs. The principles, characteristics, and legal basis of regulatory programs for medical devices will be discussed. • **Conformity assessment of medical devices:** This module will address the characteristics and principles involved in the conformity assessment of medical devices. The Cuban experience will be described, as well as recent changes in this process, taking into account recently approved WHO guidelines on the competencies of reviewers of premarket processes for medical devices. • **Post-marketing surveillance of medical devices:** This module will present the fundamental aspects on adverse event reports by users of the Cuban health system and manufacturers of medical devices, as well as the elements of patient safety that affect optimum post-market surveillance.

General work plan and proposed time frames	**Objective 1:** **Estimated implementation period**: Eight (8) months • **Phase I**: Four (4) months Update the current state of medical device regulation in the 16 member countries of the Working Group. • **Phase II:** Four (4) months Apply the instrument to generate information on medical device regulation in the remaining countries of the Region. Establish mapping of medical device regulation in the entire Region **Scope**: 35 countries of the Region. **Indicators:** • Number of participating regulatory authorities / Number of regulatory authorities in the Region **Objective 2:** **Estimated implementation period**: Six (6) months per cohort **Scope**: Two cohorts per year, each with 100 spaces available to the 35 countries of the Region. **Tutors**: 10 per cohort. **Indicators:** • **% retention**: Number of registered professionals / Number of certified professionals. • **People trained**: Total number of people trained / Total number of people scheduled for training in the period The translation of documents required for implementation of activities in 2016 will be supported by INVIMA.

Proposed project leader	Center for State Control of Medicines and Medical Equipment and Devices (**CECMED, Cuba), together** with the National Institute for Drug and Food Surveillance (**INVIMA, Colombia),** with the support of the Medicines and Health Technologies Unit of the Pan American Health Organization (PAHO), the Regional Advisor on Health Technologies, and the Regional Working Group on Medical Device Regulation
Proposed sources of expertise/ financing	**Specific objective 1**: Review, update, and adjust the basic indicators with regional mapping of medical device regulation in the 35 countries of the Region (Regional Working Group + remaining countries) In 2017 it is hoped that, as part of the specific agreement with PAHO (within the framework of the technical cooperation agreement to be signed by INVIMA and PAHO in 2016), the necessary resources will be included to finance the regional mapping activities. The translation of documents required for implementation of activities in 2016 will be supported by INVIMA. **Specific objective 2**: Strengthen regional regulatory capacity on devices through two (2) courses: Basic course on regulation of medical devices (CECMED); and Technology surveillance (INVIMA) The Technology Surveillance Group of the Medical Devices Office has seven professionals with experience and training in post-marketing surveillance of medical devices, public health, patient safety, quality health systems, preventive and reactive methodologies for the analysis of adverse events,[3] management of biomedical equipment, health technology assessment, and virtual training as tutors. This initiative will have the support of seven (7) professionals who will devote four (4) hours per day to tutoring. The platform was developed by INVIMA and CECMED and will be used by the 35 countries of the Region, with 100 spaces available for professionals to register each semester. For the in-person phase, INVIMA will cover the costs through national projects with stakeholders.
Relevant documents at national and international level	• Final Report: IV Meeting of Regulatory Authorities for the Strengthening of Regulatory Capacity on Medical Devices in the Region of the Americas. PAHO. 27-29 October 2015. • Resolution WHA 67.20 on Regulatory System Strengthening for Medical Products. WHO. 2014. • Clinical risk management: systematic review of the literature. • Operational manual on proactive technology surveillance

[3] **Methodologies**: Failure Modes and Effects Analysis (FMEA), London Protocol, Root Cause Analysis, Five Whys, Shell, and Human Factors Analysis and Classification System (HFACS).

	• Results of pilot proactive surveillance in five hospitals in Colombia 2012 • AMFES database: https://www.invima.gov.co/avance-de-la-vigilancia-proactiva-en-colombia/192-tecnovigilancia/informacion-general/3768-banco-de-amfes.html • Martínez Pereira DM, Ríos Hernández M, Ballenilla Rodríguez TM, Álvarez Rodríguez Y, Suárez Rodríguez E, Santos Alonso JM, et al. Programa Regulador de Equipos Médicos. Experiencias en Cuba. Havana: SIMAR; 2003. • Centro de Control Estatal de Equipos Médicos. Reglamento para la Evaluación y el Control Estatal de Equipos Médicos. Martínez Pereira DM, Delgado Ribas S, Suárez Rodríguez EA, (coord.) Havana: Elfos Scientiae; 2009. • Regulating Conformity Assessment of Medical Devices, approved January 2016. • Training manual on surveillance of medical equipment.