Project Proposal for Steering Committee consideration
(Please submit to PANDRH Secretariat - PAHO)

Proposed title of the area/project	Network for sharing information in the Americas on global regulatory convergence initiatives (Cross-cutting area: relationship with other global harmonization and regulatory convergence initiatives)
Initiator	ANVISA / Brazil
Purpose and Rationale (including a reference to one or more of the goals or objectives of the PANDRH Strategic Development Plan)	<u>Purpose</u> Keep the NRAs of the Americas up to date with strategic information regarding regulatory issues and trends, through the communication and interaction among designated focal points, with the goal of providing tools that might be used nationally to improve regulatory processes. <u>Rationale</u> As stated in the PANDRH Strategic Development Plan 2014-2020, the current environment of global health requires the renewal of international cooperation to develop national, regional, and global health surveillance systems for medicines and technologies under the coordination and leadership of the NRAs. PANDRH Member States are required to work together towards the common goal of strengthening regulatory capacity, through collaborative processes, with the purpose of reaching further convergence in their processes, functions, and regulatory results. This regulatory convergence requires stepping up the cooperation between the countries and the NRAs for developing regulatory systems, sharing experiences and information on health regulatory processes. Given that not all NRAs in the Americas have the opportunity to be involved in global harmonization and convergence initiatives involving countries outside the Americas, they could benefit from the fact that some countries in the Region actively participate in these initiatives, which can share strategic information with regional partners, advancing their knowledge on global regulatory trends and practices. <u>Alignment with goals/objectives</u> This activity is in line with the goals of the PANDRH Strategic

	Development Plan 2014-2020, since it aims at facilitating the exchange of information and experiences between the NRAs in the Network and other NRAs outside the Region, in order to contribute to worldwide regulatory convergence. A network for sharing information in the Americas on global regulatory convergence initiatives might advance the expected results for Strategic Objective I (Promote the efficient governance of PANDRH and the active participation and cooperation of the NRAs towards regulatory convergence and harmonization), when considered the line of action "Encourage bilateral and/or multilateral ties and agreements for collaboration and cooperation among NRAs" and its expected results "Development and/or definition of mechanisms and models for cooperation among NRAs" and "Links established with other collaborators and initiatives involved in regulatory convergence/harmonization (e.g., APEC, ICH, Alba, IMDRF among others)".
Scope **(including outline of issues to be addressed and opportunities for regulatory convergence)**	<u>Issues to be addressed</u> - In the first phase, an **introduction to global initiatives on harmonization and regulatory convergence**, including elaborating an electronic list of websites with information on the major fora that elaborate guidelines on medicines and medical devices for regulatory purposes, followed by a presentation. The presentation will focus on details about a few (3-5) global initiatives. The electronic list will be very objective and will direct to the specific websites where essential information on which are the existent groups, including details of membership, organization, issues addressed, how to get updated information, opportunities for participation / inputs from NRAs may be found. This list will be uploaded at PRAIS and can be used as a permanent source of information for internal consultations by NRAs. All NRAs of the region of the Americas will have access to the information. - In the long-lasting phase, the Project Leaders will organize **opportunities for sharing strategic information regarding regulatory issues and trends,** based on specific demands from NRAs or suggestions of the PANDRH Steering Committee. The Project Leaders might send reference information / documentation (when the topic only demands communication) or might propose the organization of meetings via web (when the topic requires interaction / discussion among NRAs) or

	direct the queries to the webinars/seminars already made available by the global initiatives. The information will be disseminated to all NRAs of the Americas. Opportunities for regulatory convergence The sharing of knowledge through communication and interaction among NRA focal points provides tools and information that potentially may be applied at a domestic level to improve regulatory processes, in alignment with updated regulation and practices of NRAs from outside the Americas.
General Work Plan and Timelines	**First phase** (0-6 Months) - Development and approval of TOR for the focal point network, with details on its functioning and membership. All NRAs of the Americas will be invited to indicate their focal points. - Introduction to global initiatives (presentation of key global initiatives and awareness of the electronic list and resources). Presentation will be open to all NRAs of the Americas. **Long-lasting phase** - Sharing of strategic information regarding regulatory issues and trends (through meetings via web and documents) among focal points, on demand or by suggestion of the Steering Committee.
Proposed Leader of Project	ANVISA / Brazil FDA / United States of America HC / Canada
Proposed sources of necessary expertise / Funding needs	Meetings via web to be maintained by the existing tools available from the PANDRH Secretariat, with the participation of NRA focal points and, eventually, of international speakers (no specific cost involved). TOR and electronic list to be developed by Project Leaders (no funding needed).
Relevant existing documents at national level, as well as in international bodies	Mapping developed by EMA on international initiatives on drugs submitted to ICMRA; Websites of international initiatives that elaborate guidelines on medicines and medical devices.