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

Proposed title of the area/project	**Assessing CPP requirements for drug registration processes in the Region of the Americas towards more timely access to medicines and more convergent regulatory approaches.** **Cross-cutting areas**: Authorization, Registration and Licensing of products and facilities and Good Regulatory Practices and Regulatory Sciences
Initiator	Latin America Federation of the Pharmaceutical Industry - **FIFARMA**
Purpose and Rationale (including a reference to one or more of the goals or objectives of the PANDRH Strategic Development Plan)	**<u>Purpose</u>** Promote the **exchange of experiences and technical views** between NRA and the Pharmaceutical Industry in relation to Certificate of Pharmaceutical Products (CPP) and previous registration* requirements in LatAm regulatory systems with the objective of **assessing** these requirements from a sanitary perspective and, if appropriate, **identifying opportunities to update regulatory systems towards more timely access to medicines and more convergent approaches** to those requirements. * **Previous registration requirement refers exclusively to the requirement existing in several national regulatory frameworks in the Region of Americas that the drug has to be previously registered/approved in the originating/exporting/market authorization holder country before local submission or local decision.** **<u>Rationale</u>** The regular assessment and update of regulatory frameworks is a key step to respond to evolving health needs. Timely access of new health technologies to patients is broadly recognized as a relevant pillar of health policies, as well as the requirement that those technologies meet sound scientific technical standards ensuring their safety, efficacy and quality (PANDRH Strategic Development Plan 2014-20). The regulatory systems and regulatory authorities in the Region of the Americas have been developing over decades through the adoption of a number of measures to improve their capacity of ensuring the quality of the products and services under their jurisdictions. This involves the update of technical guidelines, the improvement of the authorities' structure and the rationalization of administrative procedures for the submission and review of new technologies, notably drugs dossiers. Industry and National Regulatory Authorities (NRA) can and should collaborate in this regard, preserving their respective legitimate missions and goals and keeping the patient as the ultimate reason of their activities. The maintenance of permanent dialogue for the assessment and update of regulatory frameworks is one of the concrete measures that can contribute to the

	objective of ensuring patients timely access to drugs and treatments in general. The majority of regulatory frameworks in the Region require that certain documentation be provided for new medicinal products and/or variations that show the product has been previously approved in the originator/exporter/market authorization holder country, which is most commonly the Certificate of Pharmaceutical Product (CPP) established by WHO's certification scheme on the quality of pharmaceutical products. The CPP requirement varies in the Region: it can be a requirement for the submission of a dossier for medicines registration, for renewals or for a post-approval variation dossier. It can also be a requirement for the NRA's final decision on the drug application or even a non-mandatory document, submitted only to support the dossiers review. In some of these situations, the previous registration and the CPP requirement prevent that countries in Latin America participate of the so-called first submissions wave and expand the gap between first global submissions and submissions in the Latin America, delaying the availability of the treatment in the Region. The assessment of the CPP and the previous registration requirements in view of the current regulatory maturity of certain Latin American regulatory systems and new informative tools available with access to information related to the drug status from authorities of global reference, as EPAR (European Public Assessment Reports), could contribute to more timely access of patients to drugs in the Region. In addition, this assessment and the seeking for alternatives that could eliminate or mitigate the time gap between global submissions and submissions in Latin America without any harm or limitation to the decision making process of NRAs could certainly have positive impacts on the NRA and Industry's management activities, reducing their administrative burdens. The adequate mapping of these requirements according to national regulatory frameworks and the identification of the sanitary value attributed to it by the NRA could give raise to ideas on how to meet drugs' safety, efficacy and quality standards without delaying in some cases the availability of treatments in the Region. **Alignment with goals/objectives of PANDRH Strategic Development Plan 2014-2020** PANDRH Strategic Development Plan 2014-2020 recognizes as cornerstones of public health functions the formulation of public policies designed to solve health issues and the access of all populations to appropriate, effective, and affordable health care. It also recognizes regulation as one of the public health's basic functions and that the access to medicines has a direct relation to the efficiency of regulatory frameworks. The regular review and assessment of regulatory requirements in view of evolving health needs is an important step so that regulatory frameworks are kept updated and perform efficiently. The exchange of information and experiences between the PANDRH members and, if appropriate, with other NRA, both in a broad scale and for punctual assessment of regulatory models or requirements responds to the need of cooperation for effective health

	promotion. The diversity of ways that CPP and need of previous approval requirements are established in the Region creates a notable opportunity for the exchange of information on this topic among PANDRH members and to discuss whether and how such requirements are contributing to the efficient performance of the essential regulatory function of drugs registration. In addition, following Objective II of the Strategic Plan, PANDRH Steering Committee defined as cross-cutting areas for the development of projects "Authorization, Registration and Licensing of products and facilities and Good Regulatory Practices and Regulatory Sciences". The present proposal relates to a widespread requirement for drug registration in the Region with significant impact on the timely availability of drugs and that may benefit from a collective effort seeking opportunities for improvement focused on the principle of rationalization, which implies convergence and efficiency, proportionality and reactivity of the good regulatory practices.
Scope **(including outline of issues to be addressed and opportunities for regulatory convergence)**	<u>Issues to be addressed</u> There is not a comprehensive map of the CPP and previous approvals requirements established at the national levels by American Countries. These requirements are historically established by national regulations particularly in Latin America and no common effort has been made yet by relevant stakeholders in the Region to assess their adequacy to the state of art of information tools, development status of the NRA and evolving health needs. The collaboration of PANDRH members to make this map and assessment and to identify opportunities of updating and improving those requirements with focus on patient needs and good regulatory practices may result in more convergent regulatory approaches to CPP and previous registration requirements and mitigate time gaps between the drug availability in the Region and in more technologically developed countries. <u>Opportunities for regulatory convergence</u> There is a significant diversity of CPP and previous registration requirements in drug regulatory frameworks of PANDRH members. The mapping of this scenario in the Region of Americas, the exchange of information between NRA, Industry and, occasionally, other relevant stakeholders, and the assessment of the need of improvement and update of such a requirement can give raise to common approaches to the "CPP and previous registration" topic in the Region. The project may lead to the identification of points of *consensus* related to the CPP and previous registration requirements among NRA in the Region and, in this sense, may pave the way to the adoption of more convergent regulatory models in relation to this particular requirement for drug registration.

General Work Plan and Timelines	- **Step I**: develop a comprehensive mapping of how PANDRH NRA members' regulatory frameworks provide for the CPP and the previous registration requirement, with the indication of the relevant norms underpinning these requirements. **Due date**: 6 months after project's approval; - **Step II**: development of a report on the current scenario in relation to CPP and previous registration requirements in the Region of Americas and the views of NRAs, Industry and, occasionally, other stakeholders with appropriate expertise, on the current sanitary role of such requirements. **Due date**: 3 months after Steps I completion; - **Step III**: based on the report, identification by participating NRA and the Industry of opportunities for updating and improvement in the current regulatory requirements related to CPP and previous registration by the originating/exporter/market authorization holder country in drugs' registration processes. **Due date**: 3 months after Step III completion; **- Step IV**: preparation of a report with suggested updating and improvement opportunities, and, if appropriate, other stakeholders' views on those opportunities. **Due date**: 3 months after Step III completion; **- Steps V**: submission of the report to PANDRH Steering Committee so that updating and improvement opportunities of current regulatory requirements related to CPP and the previous registration requirements can be discussed and, if appropriate, a decision on future steps to explore to those opportunities can be submitted to PANDRH Conference. **Due date**: immediate PANDRH Steering Committee meeting after completion of Step IV.
Proposed Leader of Project	CECMED and FIFARMA
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 PANDRH's members focal points specifically nominated for this project and, occasionally, of international speakers (no specific cost involved). No funding needed.
Relevant existing documents at national level, as	• **Local/NRA regulatory frameworks**, in the part related to CPP and previous registration in the originating/exporter country/market authorization holder requirements for the registration or life cycle management of drugs. • WHO Drug Information article – **The WHO CPP Scheme in today's regulatory environment: is it time for change?**

well as in internatio nal bodies	http://www.who.int/medicines/publications/druginformation/issues/WHO_DI_29-4_QualityMeds.pdf?ua=1 • **WHO Cert Scheme on the quality of pharmaceutical products moving in international commerce Q&A** (draft for comment: http://www.who.int/medicines/areas/quality_safety/quality_assurance/WHO_QAcertif_scheme_2015-Revision_QAS15-623_02062015.pdf?ua=1 • **Relevance of a Certificate of Pharmaceutical Product for Registration and Life Cycle Management of Imported Drugs**. (Master Thesis/Academic paper) http://dgra.de/media/pdf/studium/masterthesis/master_sahl_a.pdf • **PANDRH's Technical Document n. 1, of 2010** (model document for the registration of vaccines) • **PANDRH's Technical Document n. 10, of 2013** (model document for the registration of drugs) **How has the evolution of the global pharmaceutical market affected the use of WHO Certificates of Pharmaceutical Product (CPP)**. In Regulatory Rapporteur, vol. 9. N. 4, April 2012.