Call for Projects
VIII PANDRH Conference
Mexico City October 19-21, 2016

Project Proposal
For consideration by the Steering Committee

Proposed title for the area/project	**Non-prescription drugs: From the traditional model to new regulatory feedback scenarios.**
Proponent	National Drug, Food, and Medical Technology Administration (ANMAT, Argentina), together with the National Health Surveillance Agency (ANVISA, Brazil), the National Drug and Food Surveillance Institute (INVIMA, Colombia) and the Federal Commission for Protection against Health Risks (COFEPRIS, Mexico) with the support of producer associations: Latin American Association for Responsible Self-medication (ILAR).
Objective and rationale (with reference to one or more of the objectives of the PANDRH Strategic Development Plan)	**General objective:** Design and conducting **field research** on the habits of non-prescription drug users, with a view to implementing actions aimed at resolving certain common problems in the Region. **Specific objectives:** – Improve the understanding of the context of non-prescription drugs in the countries of the Region, given people's increasing access to information on this kind of products. – Design and implement regulatory tools coherent with the use of new information technologies and adapted to this category of medicines. – Foment health education activities aimed at the general public, focusing on good practices in the use of non-prescription medicines. – Identify strengths and opportunities in this category of medicines for the health system of each country in the Region. **Rationale:** **Access to health information** through **new technologies** is an indisputable fact. This has affected the way people make decisions about their health. These changes present regulatory agencies with the challenge of keeping continually up to date in order to make decisions increasingly coherent with the reality of non-prescription drug users. For this reason, in 2013, the regulatory agencies of Latin America [Argentina **(ANMAT)**, Brazil (**ANVISA**), Chile **(ANAMED)**, Colombia (**INVIMA**), and Mexico

	(**COFEPRIS**)] initiated a series of meetings to compare experiences on subjects of interest and importance with regard to non-prescription drugs. At these meetings, initial research was jointly designed and conducted on subjects such as sources of product recommendations, understanding labels, and the impact of advertising, thus laying the groundwork and establishing a precedent for this project. It should be emphasized that Latin America has specific characteristics and idiosyncrasies when compared to other regions, with some countries having advanced health systems that are seen as models. In conclusion, given the **need to optimize each country's specific regulations** in this area, the agencies involved make it their mission to **innovate and strengthen good regulatory practices** to reflect current user needs and demands, as well as the impact of new information technologies on the use of these products. Accordingly, it is necessary to strengthen **control and surveillance** activities by sharing experiences and knowledge in the Region. All of the above **is consistent with the objectives of the PANDRH Strategic Development Plan**, with a view to adding value in the context of non-prescription drug use.
Scope (including points that should be addressed and opportunities for regulatory convergence)	This innovative vision should address the following points, among others, at the regional level: - Brand names (including umbrella brand names) - Reclassification (switching) - Prospectus/ labeling/ product insert/ packaging - Presentation/ Contents per unit of sale - Advertising - New accesses to information and feedback - Field research Addressing these key areas will create the right conditions for common spaces and lines of work that offer opportunities for regulatory convergence in the Region. The goal will be to achieve standardized criteria, in addition to the documents prepared by the working group. Project implementation will require the use of virtual tools for the exchange of information, such as video conferences and the Regional Platform on Access and Innovation for Health Technologies (PRAIS).

General work plan and proposed time frames	Work will be done in person, at meetings that will address the topics related to the proposed goals. These meetings will be held semiannually and virtual meetings will also be held, if appropriate. Annual goals will be set, consistent with the achievement of the objectives proposed in each meeting. The key tool will be field research and the sharing of experiences among agencies. Targets and goals will be based on: a) Creating a diagnostic and situational map of the priorities of each NRA involved. b) Correlatively evaluating each NRA's capacities and available resources for project implementation. c) Monitor implementation of the work plan in order to demonstrate and evaluate its effectiveness in relation to its cost and sustainability. d) Evaluate the process of developing the work plan in order to determine its effectiveness, efficiency, and corresponding impact on the NRAs in the Region so that, if necessary, corrective action can be taken on the lines of work, according to the importance of the original strategic area. .
Proposed project leader	National Drug, Food, and Medical Technology Administration (Argentina).
Proposed sources of expertise/ financing	**Expertise:** – National regulatory authorities of regional reference (NRAr) – National Academy of Pharmacy and Biochemistry, Argentina – 2nd Chair of Pharmacology of the Faculty of Medicine, University of Buenos Aires, Argentina – Consultant, IPSOS, Argentina – National Association of Industrial Entrepreneurs of Colombia (ANDI) **Financing:** – Producer associations: Latin American Association for Responsible Self-medication (ILAR) in collaboration with participating NRAs.
Relevant documents at the national level, as well as international organizations	– WHO. (1985). The rational use of drugs: Report of the Conference of Experts, Nairobi. – WHO. (1988). Ethical criteria for medicinal drug promotion, Geneva. – PANDRH Working Group on Drug Classification, Definition and Criteria to Apply to Over-the-Counter (OTC) Drugs, IV Pan American Conference for Drug Regulatory Harmonization, 2005. – PANDRH Working Group on Promotion of Medicines, Ethical Criteria Promoting, Advertising and Publicizing Pharmaceuticals, V Pan American Conference for Drug Regulatory Harmonization, 2013. – Specific regulations on the registration, authorization, marketing, advertising, and control of non-prescription drugs in each member country. – Field studies in the Region, conducted at the public and private levels. – Discussions and analyses carried out in working groups in ILAR meetings, which, though unpublished, set precedents in terms of identified needs in the Region. (Reports on meetings are available.)

Notes and/or comments on the review by the Steering Committee	– Participation in this project is open to other PANDRH agencies that wish to join. There are progressively fewer geographic barriers in the Region, due to the new technologies. – This project sets out to identify common problems and, based on this, to produce field data and products on strategies to improve regulations, enabling each agency to optimize aspects of its regulations and allowing other countries to follow suit. – It should be clarified that the sources of information on which this project is based were designed with the participation and oversight of the agencies, and the project was carried out by internationally respected consultants.
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