Ireland 2018

18th International Conference of Drug Regulatory Authorities

Dublin, Ireland | 3–7 September 2018

Pre IDCRA Workshop 2: Certification of Pharmaceutical Products: Is it still "fit for Purpose" in a modern environment

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

World Health Organization

edqm
European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Moderated Panel Discussion

Panellist: Celeste Sánchez, PhD

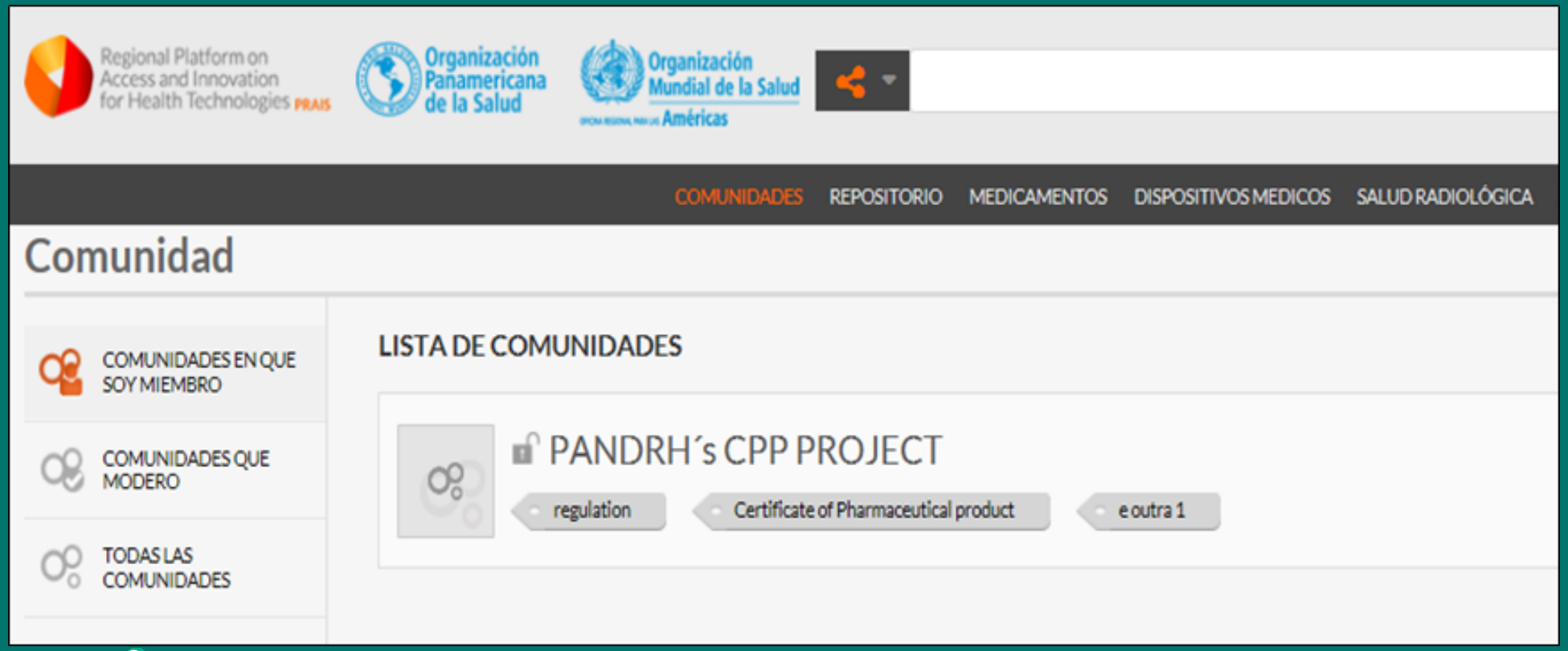
PANDRH's Project "Assessing CPP requirements for drug registration processes in the Region of the Americas, towards more timely access to medicines and more convergent regulatory approaches"

General overview of the CPP project

- Coordinators: CECMED (Centre for State Control of Medicines, Medical Equipment and Devices) and FIFARMA (Latin American Federation of the Pharmaceutical Industry)
- PANDRH Steering Committee Approval Date: Dec 6th 2017;
- Project's kickoff meeting date: Feb. 27th, 2018;
- Project's general purpose : The mapping of the regulatory requirements related to the submission of a Certificate of Pharmaceutical Product for the registration of drugs in the region, evaluating the sanitary value of this requirement, considering the national needs and perspectives, and to contribute to identify the opportunities for improvement in the CPP requirements towards a more timely access of drugs and more convergent approaches to regulation.

Visibility of the PANDRH's CCP Project. PRAIS Community

PRAIS access: **http://prais.paho.org/pt/inicio-2/**



CPP project's five general steps

STEP I

Information for comprehensive mapping of CPP-related requirements for drug registration in the region of he Americas.

Due Date: 6 months after project's approval

STEP II

Development of a **report on the current regional scenario** in relation to CPP requirements and views on the sanitary roles of such requirements.

Due Date: 3 months after Step I completion

STEP III

Based on the report identification by participating PANDRH Members of **opportunities for updating and improvement** in the current regulatory requirements

Due Date: 3 months after Step II completion

STEP IV

Report preparation with suggested updates and opportunities.

Due Date: 3 months after completion of Step III

STEP V

Submission of the report to **PANDRH Steering Committee**, so that updating and **improving opportunities can be discussed and explored.**

Due Date: Immediate PANDRH SC meeting after completion of Step IV

CPP questionnaire/survey with 10 sections

1. Submission of new drug applications/ new pharmaceutical products
2. Submission of renewal applications
3. Submission of post-approval changes/ variations
4. CPP form/document content
5. Evaluation of the CPP by the NRA
6. Assessment of the Previous Registration in the Country of Origin *(applicable when a registration is required in the Country of Origin)*
7. Effects of MA/Registration cancellation or suspension in CPP's issuer-country
8. CPP and marketing status of the product
9. Other Relevant Information
10. Particular aspects related to the issuance of CPP (app. to CPP's issuers)

Survey for the Collection of Information on Regulations and Practices of the CPF in the Region of the Americas

Survey Tool: Survey Monkey available in Spanish and English:

https://es.surveymonkey.com/r/Survey_CECMED_FIFARMA_CPF

https://es.surveymonkey.com/r/Survey_CECMED_FIFARMA_CPF?lang=en

Convened to participate 30 NRAs and the Caribbean Regulatory System (CARPHA) and more than 15 Industrial Associations in the region

It will be a report with the mapping of CPP regulation & practices in the Region together with a structured discussion on the sanitary role of CPP and related practices/regulation in the project's next stage

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Advantages and Challenges of Scheme vs. Some Preliminary Results

- CPP **is used** by NRAs of Las Americas for the Registration/Renewal and Variations of Pharmaceutical Products and it **is always assessed** by NRAs but it doesn't means that there are fast tracks for dossiers with CPP, nor abbreviated dossiers
- The **previous registration** declared in CPP is a requirement for registration in the new country, mainly in origin country (where is manufactured the finished product), but it is also accepted a CPP from a non manufacturing country
- To have **lists of recognized NRAs** for accepting CPPs is not generalized, but there are several NRAs with this practice
- CPP is required as a requirement for appliances, **at the beginning of the registration process**, and the **status of commercialization of the product** in the issuing country impact the process of registration
- The status of **GMP declared in CPPs is recognized** by NRAs

Advantages and Challenges of Scheme vs. Some Preliminary Results

- Information about the product **is not attached** to CPP -Patient Information Leaflet (PIL) and/or the Summaries of Product Characteristics (SPC)-
- Around 50 % of NRAs are **accepting electronic CPPs**
- **Electronic CPPs aren't issued** by the most of NRAs
- The most of NRAs request CPP to be notarized, authenticated, legalized
- **No clear timelines for CPP issuance** after a request is submitted by the marketing authorization holder
- The **staff of NRAs haven't received particular training** about the WHO Scheme/CPP
- The most of rules about CPP are established by **national regulations**, but rules of NRAs are relevant for some practices

Current actions of Regulatory Improvements that favor changes and optimization in the use of the CPP and the Scheme

- Process of strengthening the regulatory systems
- Process of Global Benchmarking of Regulatory Systems
- Future list of NRAs of WHO
- Implementation of Good Regulatory Practices which emphasizes efficiency in NRAs
- Actions in favor of regulatory convergence which results in consistency
- Process of Revision of the WHO Certification System itself, and feedback from for different forums like ICDRA, which contribute to align the scheme and the CPP to the new times and that its update is of benefit for the timely access of medicines for patients, better understanding and practices of the NRAs and less regulatory burden for the pharmaceutical industry

Thank You

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