PANEL E: Regulating supply chain and its impact in Health Systems

PANDRH Project update: Assessing CPP requirement for medicines registration – presentation of the preliminary outcomes

Moderators:

- CYNTHIA LUWIS (JAMAICA)
- MURILO FREITAS (OPS/OMS)

GENERAL OVERVIEW OF THE CPP PROJECT

- **Project's title**: Assessing CPP requirements for drug registration processes in the Region of the Americas towards more timely access to medicines and more convergent regulatory approaches
- **Project's general purpose** : **mapping** of the regulatory requirements for the Certificate of Pharmaceutical Product required for the registration of drugs in the region, **evaluating** the benefits of this requirement, considering the national needs and perspectives, and to contribute to **identify the opportunities to improve the CPP requirements** in order to have **timely access** of drugs and **more convergent approaches to regulation**.
- **Coordinators**: CECMED (Centre for State Control of Medicines, Medical Equipment and Devices/Cuba) 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;

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. National Regulatory Authorities (NRA) that issue CPP

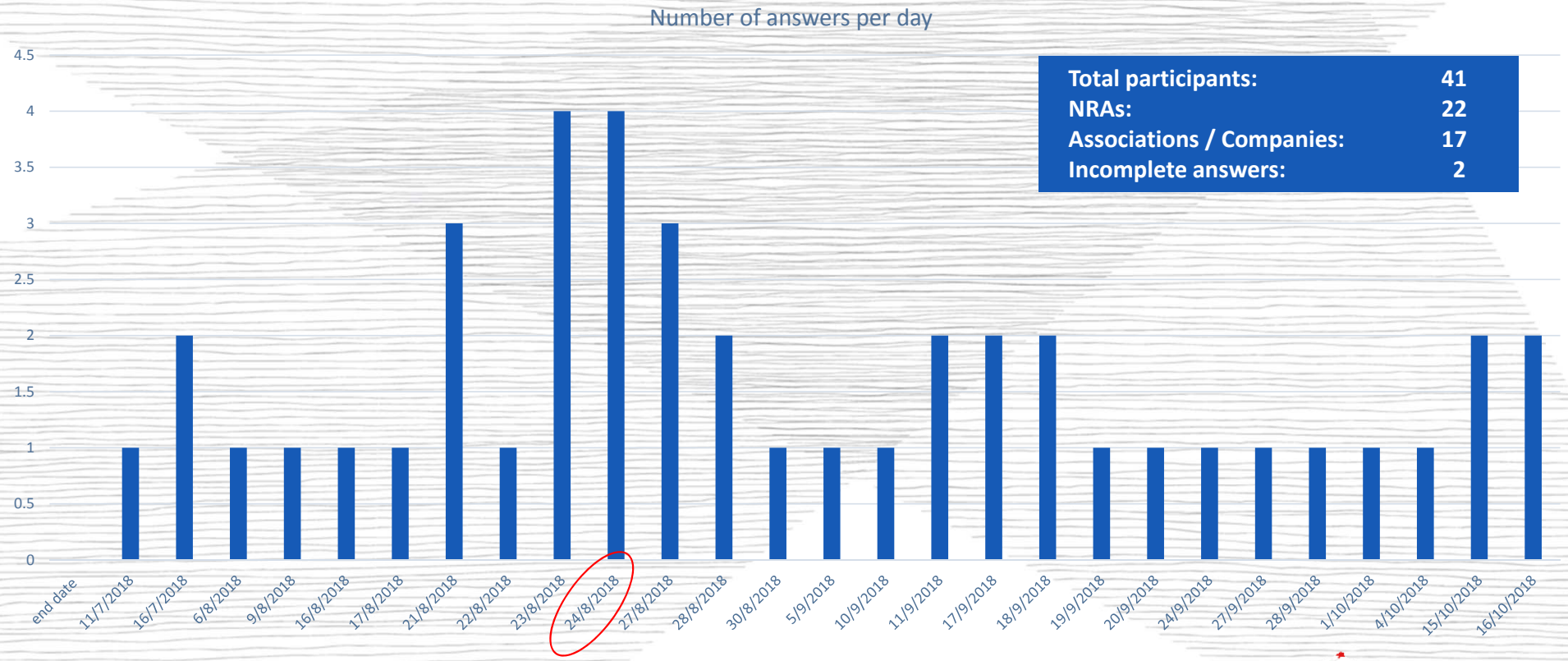
CPP project's activities performed so far

- **Coordinators' meetings:**
  - Project's kickoff meeting: Feb. 27th, 2018;
  - Coordinators' meetings: **April** 5th, 2018, **July** 5th, 2018, **August** 13, 2018, **October** 11th, 2018
- **Project's promotion and communication activities:**
  - **Project's webinar**: April 19th, 2018;
  - Meeting with **local Trade Associations**: July 19th, 2018
  - **Mexican Convention of Sanitary Officers of the Chemical-Pharmaceutical Industry**, held in Querétaro, Mexico, on August 22-24th , 2018 and organized by The National College of Pharmaceutical Chemists and Biologists of Mexico;
  - **International Conference of Drug Regulatory Authorities (ICDRA)** of the World Health Organization (WHO) held in Dublin, Ireland, from September 3-4, 2018, as part of the program of the **Pre-ICDRA Meeting**;
  - Article on PANDRH's CPP project published in **DIA Global Forum**, May Issue.

PAHO/WHO

Final Deadline:
31/10/2018

DATES OF RESPONDENTS ANSWERS

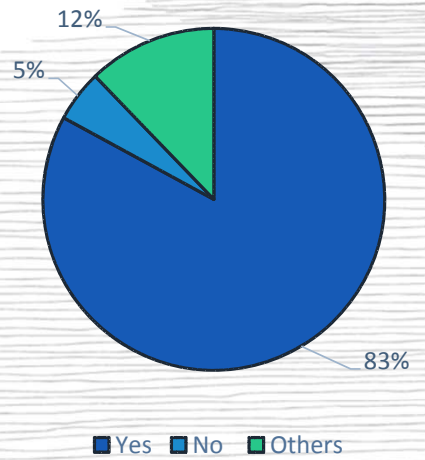


Total participants:	**41**
NRAs:	**22**
Associations / Companies:	**17**
Incomplete answers:	**2**

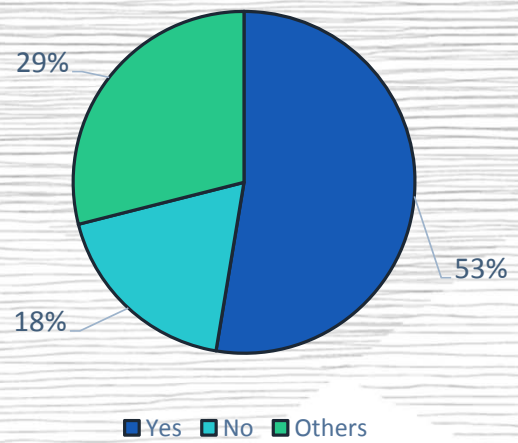
PAHO

CPP requirement for drugs registration, post-registration changes and registration renewal

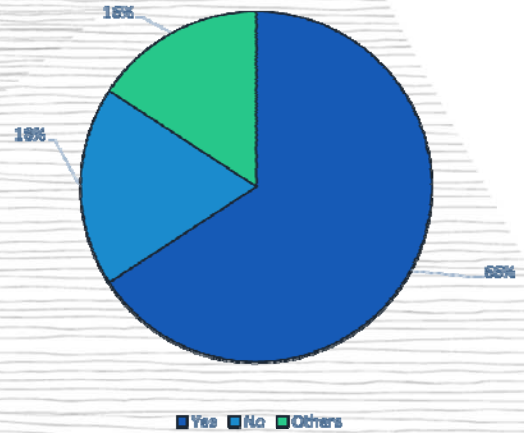
Is a CPP required for new drug submissions/registration of a new pharmaceutical product/new registration in the country?



Is a CPP required for the requests of variation of the registration/post-approval changes of pharmaceutical products?



Is a CPP required for the renewal of the registration of pharmaceutical products?



SOME PRELIMINARY RESULTS

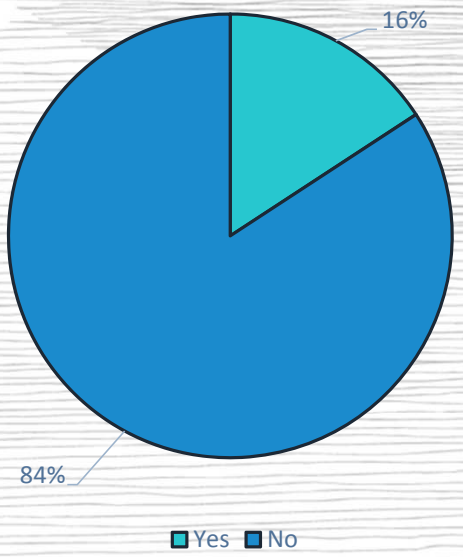
- CPP is always assessed by NRAs but it doesn't means that there are fast tracks for dossiers with CPP, nor abbreviated dossiers
- The previous registration declared in CPP is a requirement for registration in the new country, mainly in origin country (where is manufactured the finished product), but it is also accepted a CPP from a non manufacturing reference 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 applications, 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 almost all NRAs

SOME PRELIMINARY RESULTS

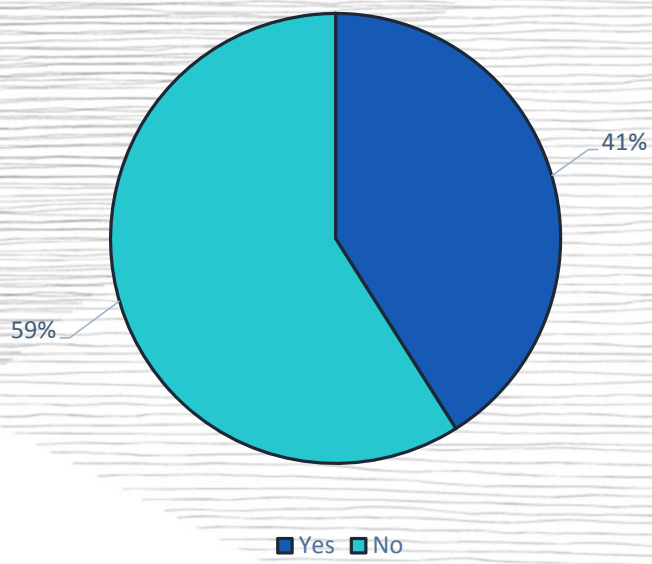
- Information about the product is not attached to CPP -Patient Information Leaflet (PIL) and/or the Summaries of Product Characteristics (SPC)-
- Electronic CPPs aren’t issued by the most of NRAs
- The majority of NRA's request CPP to be notarized, authenticated, legalized
- No clear timelines for CPP issuance after a request is submitted by the marketing authorization holder
- Most of the requirements of CPP are established by national regulations, but rules of NRAs are relevant for some practices

CPP in electronic format

Does the NRA issue CPP in electronic format?

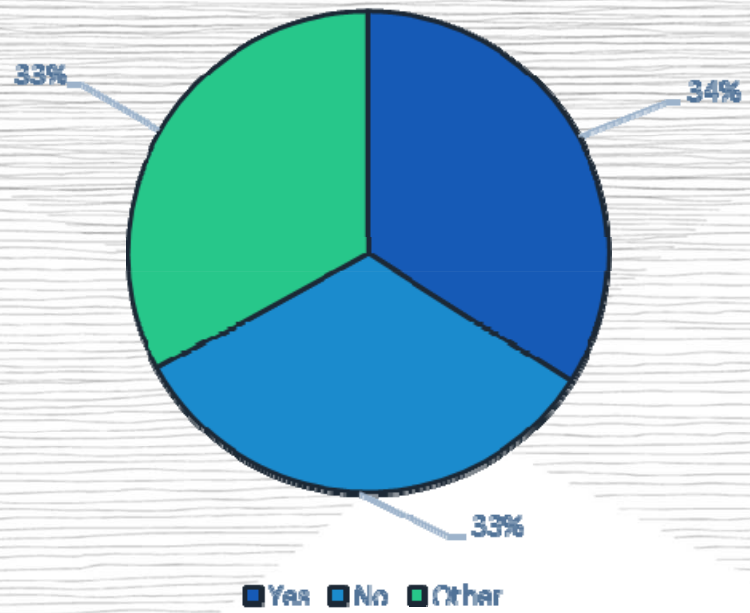


Does the NRA accept CPP in electronic format?



Training on the WHO Certification Scheme

Has the NRA's relevant staff been trained on the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce?



CURRENT ACTIONS OF REGULATORY IMPROVEMENTS THAT FAVOR CHANGES AND OPTIMIZATION IN THE USE OF THE CPP AND WHO's 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, PANDRH, WHO, etc., 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

CPP project's next steps within the the next 3 months

- Extended deadline for answers to the CPP survey: October 31st, 2018
- Survey's data base "cleaning"
- Preparation of the mapping report
- Delivery of the mapping report to PANDRH Steering Committee
- Initiation of the structured discussion on CPP-related practices and requirements in the Region of the Americas

VISIBILITY OF THE PANDRH's CCP PROJECT

PRAIS COMMUNITY

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

Thank you!