EXECUTIVE REPORT

ASSESSING THE CERTIFICATE OF PHARMACEUTICAL PRODUCT (CPP) REQUIREMENTS FOR THE DRUG REGISTRATION PROCESSES IN THE REGION OF THE AMERICAS, TOWARDS A MORE TIMELY ACCESS TO MEDICINES AND MORE CONVERGENT REGULATORY APPROACHES

2020

Project of the Pan American Network for Drug Regulatory Harmonization (PANDRH Network) jointly coordinated by CECMED and FIFARMA

PANDRH
Pan American Network for Drug Regulatory Harmonization

CECMED
Centro para el Control Estatal de Medicamentos, Equipos y Dispositivos Médicos

FIFARMA

INTRODUCTION

This document presents a summary of the analysis of the results for the assessment of the requirements and practices for the acceptance, use and issuance of the Certificate of Pharmaceutical Product (CPP) as a key document in the regulatory processes of medicine registration in the region of the Americas, and in the legal basis supporting its use.

The ultimate aim is to summarize the impact of the CPP in the registration of the pharmaceutical products in the region in order to identify convergences and divergences, to generate points of consensus and to promote good practices and actions that allow for mitigating the time gaps in the availability of the medicines between the countries of the regions and those which are more technologically developed.

The Certificate of Pharmaceutical Product

The CPP is the main document in the World Health Organization (WHO) scheme for the certification of those pharmaceutical products that are subject to international commerce. It represents a tool that allows the NRAs to share information and to avoid the duplication of efforts. The CPP, introduced in 1975, has been widely used in the submission processes of registration applications for the import of medicines around the world. The main purpose is to be an instrument that enables to contribute to the assurance of the standards expected in the quality of the medicines, communicating key information regarding the imported/exported medicines. After years of experience, the concept of CPP has faced challenges and distinctions resulting from the evolution of science, regulations and the international pharmaceutical markets. Because of this, discrepancies have arisen based on the different interpretations and uses of the CPP, triggered by the increasing complexity of the supply and manufacturing chains, the new types of products, the diversity related to regulations, legislations and others, which cause differences in the application of the document in different countries.

The PANDRH Network and the project

The Pan American Network for Drug Regulatory Harmonization (PANDRH Network), created in 1999, is an initiative by the NRAs in the region of the Americas to support the pharmaceutical regulation processes in the region. The founding members of the Network are the NRAs, the trade associations and other health technologies in the region, the Latin American Federation of Pharmaceutical Industry (FIFARMA) and the Latin American Association of Pharmaceutical Industries (ALIFAR).
The Pan American Health Organization (PAHO) acts as the Secretariat of the Network.

Considering priority areas and the objectives of the Strategic Development Plan, based on proposals that may arise from different interested parties, the Network Steering Committee assesses and approves the execution of projects, according to their potential contribution, to improve the regulatory convergence and to strengthen the regulatory capacities of the countries in the region.

In order to contribute to the discussion on the practices related to the CPP, the industry representatives identified the need for generating information concerning the region of the Americas. Therefore, through FIFARMA, the proposal of the "Assessment of the CPP requirements for registration processes of medicines in the region of the Americas, towards a more timely access to medicines and more convergent regulatory approaches" project was submitted to be assessed by the PANDRH Network members. This Project was approved by the PAHO Steering Committee in December 2017. The joint coordination of the project was in charge of FIFARMA, as the sponsor, and the Centre for State Control of Medicines, Medical Equipment and Medical Devices (CECMED) from Cuba, as a NRA of regional reference.

The purposes of the project approved were mapping the regulatory requirements related to the submission of a CPP for the registration of medicines in the region, by assessing their health value and considering the national needs and perspectives, as well as contributing to identify the opportunities of improvement for a more timely access to medicines and more convergent approaches for the regulation.

The general plan and work stages approved for the project by the PANDRH Network Steering Committee were used as a guide to carry out the study. Phase I was related to the development of an online survey, with the participation of the NRAs and industry members, to gather information on the way that regulatory frameworks regard CPP and its role in the regulatory pre-requirements, including the relevant standards supporting them. In Phase II, a report was developed on the scenario identified from a thorough analysis of the information gathered. This executive report is a summary of this document and shows the main trends.

The following phases of the project will include the identification of opportunities for updating and improving the current CPP-related regulatory requirements by the countries of the Americas. The best practices identified will be discussed with the interested parties and submitted to the PANDRH Network Steering Committee, in order to make approved recommendations available for the next PANDRH Network Conference.

All documents related to this project are available for consultation at a specific community: the Regional Platform on Access and Innovation for Health Technologies (PRAIS) of the PAHO.

Main results

The study was carried out with the collaboration of 24 NRAs, 10 participants on behalf of industry and 1 regulatory system, with answers representing 27 countries in the region.

It showed the CPP is required by 25 NRAs to register new medicines/new pharmaceutical products in the region of Americas since only Canada and the United States, although they

issue the CPP, do not request it. Most countries in the region require a CPP for all registration submissions based on national legislation requirements rather than the NRA's own rules. For Central American countries, this obligation is also specified in the Central American Technical Regulations (RTCA).

More than half of the countries responding to the survey indicate that the CPP does not need to be issued by a NRA recognized as a reference, strict or supervisory authority. However, the CPP must be issued by the regulatory authority of the product's country of origin or country of consignment.

Most countries consider that the prior registration of the product in the country of origin is mandatory. However, the region has not an entirely harmonized approach, which could be related, among other reasons, to a difference in the concept "country of origin". There is no pattern defined for the Central American countries on this particular issue.

The practice within the region is to consider the manufacturing site of the finished product as the country of origin. Another trend is not to associate the concept of country of origin with the quality control testing site (release) of the finished product. Most NRAs requiring mandatory prior registration of a product in the country of origin also request a statement of this registration status.

The vast majority of countries requiring CPPs accept them if they are issued by NRAs that have registered/approved the product, even if they are not from the manufacturing country. They also accept them when a positive assessment results from the inspections of compliance with Good Manufacturing Practices, carried out by another NRA, i.e., a third party.

The requirement for a CPP with the initial submission is almost unanimous. Most countries accept the substitution of the CPP with other documents, and most NRAs which do so state that there are conditions for this substitution. Also, almost all countries conduct detailed evaluations of drug registration applications and require complete dossiers, even if they require and receive the CPP.

As a general policy of the region, no fast track procedures are used after the submission of the CPP. The practices of Central American countries vary, so a common policy cannot be defined.

More than half of the countries responded that whenever a CPP is provided, as a requirement or voluntarily, no abbreviated files are accepted (with less documentation, information, or data). In other words, the general policy in the region is the absence of information simplification procedures for submitting a CPP.

In the case of the twelve countries claiming that they accept the use of fast track/accelerated/simplified procedures or abbreviated files, that decision is based on the recognition of certain authorities and not of the CPP. The most recognized NRAs are the following: EMA (8), FDA (8), Health Canada (5), Swissmedic (3), MHRA (3), TGA (3), PMDA (2). The remaining NRAs of regional reference (ANMAT, ANVISA, COFEPRIS, INVIMA, CECMED and ISP) are acknowledged by four countries. Central American countries show no trends because they do not report information in this question.

Most countries in the region require that the CPP meets specific conditions for applications to be assessed under accelerated procedures or for an abbreviated file to be accepted.

When evaluating data on the CPP requirement for registration renewal of pharmaceutical products, the trend can only be measured considering solely the countries with renewal procedures since this is not a common practice. The vast majority of countries in the region that conduct renewal procedures require a CPP for this purpose. This trend is not observed for the rNRAs since three of the six rNRAs using the WHO Scheme and performing registration renewals require a CPP.

Most countries requiring a CPP for renewals do so based on national legislation requirements rather than the NRAs' own rules. For Central American countries, this obligation is also specified in the RTCA.

Most countries requiring CPPs for renewals maintain the same requirements as those applied for registrations. However, there is no clear trend in the region that the CPP must be issued by the same NRA that did it so for the initial registration.

Regarding the need to submit a CPP for applications for post-approval variations and/or changes in the registration of pharmaceutical products, most NRAs in the region require it. Of all the NRAs asking for a CPP for variations, fewer countries require it for all applications (3), other countries assess the issue on a case-by-case basis (4), and most countries do it so only for specific cases (14).

The trend for countries requiring CPPs for post-approval registration variations and/or changes is to do so based on the national legislation, although the number of countries that determine it based on NRA rules is not negligible. For Central American countries, this obligation is specified in the RTCA.

The regional practices aim to keep the same CPP requirements for both post-approval changes/variations and submission of the registration application. In contrast, most Central American countries state they apply different requirements.

Within the region, the practice related to changes is not to require that the submitted CPP be issued by the same NRA that issued the original CPP. Central American countries do not follow a standardized policy for this requirement.

As regards the content of the CPP, there is no marked trend on the respective legal basis since, for some countries, the requirements are stated in the national legislation; for others, there is no specific legal provision on the content of the CPP; for Central American countries, the legal basis is provided for in the RTCA and, for a few countries, in the NRA rules. For the two countries in the region not requiring a CPP, but that issue CPPs, the form is determined by the rules of the regulatory authority.

Most countries require that the CPP includes information on the marketing status of the product. There is a slight trend for countries to require a list of all manufacturing sites involved in bulk production, packing or primary packaging, and final release of the product, as well

as information on the diluent. Most countries do not require the patient information leaflet, or instruction leaflet (IL), or the summary of product characteristics (SPC) attached to the CPP.

All NRAs surveyed report that they carry out the CPP evaluation and most of them explain that this requirement is stated in their national legislation. In the case of Central American countries, this is provided for in the RTCA.

Countries in the region report having experience with total or partial rejections, summary rejections or requests for additional information due to incomplete CPPs, rejections due to lack of product name or information regarding the marketing status, illegible information, or lack of product's qualitative-quantitative formula.

Most countries in the region require the product to have an active marketing status in the CPP provided for registrations, renewals, and changes/variations submissions. There is a slight trend for the legal basis of the requirement to be stated in the national legislation. Contrary to the regional provision, there is a trend for most rNRAs not to require this information. Most countries do not require specific information and/or requirements related to the marketing status (e.g., marketing time frame).

The vast majority of the NRAs requiring a CPP do not have particular considerations in the evaluation according to the marketing time frame stated in the document.

For the countries requiring a statement of the prior registration status in the country of origin, such status is assessed in the CPP. In turn, for the NRAs requiring prior registration of the drug in the country of origin and also requiring the marketing status be included in the CPP, the trend is to ask for additional information for submissions if the product is not marketed in the country of origin.

This assessment is mostly carried out by the NRAs following the national legislation. Concerning this issue, no clear trend is identified for the countries of Central America.

The countries in the region consider as relevant all the information contained in the sections of the CPP so as to determine the future characteristics of the drug's registration. When the CPP includes information on the GMP of the product's manufacturing site, the trend in the region is to acknowledge the GMP certification.

When considering the consequences on the CPP of the cancelation or suspension of the registration in the issuing country, the practices in the region indicate that the vast majority require the holder to notify such cancelation or suspension to the recipient NRA. For most countries, this requirement is included in the national legislation.

As a consequence of such information, the trend observed is that the registration is not automatically canceled when there is a cancelation of the registration in the CPP-issuing country, but this measure has an impact as it can affect renewals and generate adjustments to the registration. There is no clear regional trend on the impact when there is a suspension of the registration, although it is possible to assert that the registration is not automatically canceled.

Although all countries in the region are CPPs- issuing or receiving countries, regarding the training of the staff, there is lack of consensus since when training was provided, it was an in-house procedure, which does not favor a convergent regulatory approach in the region. However, most countries provide some kind of training and clarify that it is in-house because they have not been provided external training.

Most NRAs in the region do not accept the CPP in electronic format (eCPP) and are not prepared to work with such documents. However, the number already accepting it is not negligible. In Central America, practices vary; the same was found for the rNRAs. Acceptance of the eCPP is included in the national legislation for most of the NRAs that use it. Those who do not accept this format report that the impediment is their national legislation or a legal vacuum. At the same time, most countries accepting the electronic format document require additional requirements, such as apostilled document, notary certification, mandatory printing, or that the issuing authority legalizes the electronic format.

It is clear that this new CPP format is gaining ground, although current regulations do not recognize it yet. However, the study is limited and does not allow complete conclusions to be drawn regarding this practice, as it does not investigate the adoption of automated systems by NRAs, or the possibility of accepting electronic signatures, etc.

It is a common practice for the NRAs in the region, including all Central American countries and all NRAs, to require the legalization of the CPP. The general policy is to require that the embassy or consulate be located in the issuing country or in another country with diplomatic relations with the receiving or issuing country.

The vast majority of the NRAs usually set a term for the acceptance of the CPP beginning on the date of issue.

In general, NRAs only accept CPP requests from the holder of the marketing authorization or its legal representative.

In general, NRAs do not make differences between the requirements for the content of the CPP depending on the type of product (e.g., synthetic drugs, biological drugs).

Finally, the data on the characteristics identified in the CPPs of the issuing NRAs are presented. Most countries report setting deadlines for processing the application, usually from five to twenty business days, but the deadlines can be as long as two months. In nearly all cases, deadlines are set according to the NRA rules. It is not a regional practice for NRAs to issue electronic documents. Neither NRAs tend to issue them. Most CPP-issuing NRAs in the region set a validity period between one and two years for their CPPs.

The CPPs issued by ten countries of the region were evaluated in detail. For this purpose, they were compared with the standard form suggested by the WHO. The vast majority of the documents showed coincidence with the WHO standard form in terms of content of the header, product name and dosage form information, product authorization data, information regarding periodic inspections at the manufacturing site by the certifying authority, and information provided by this authority.

It is observed that, especially for the section product name and dosage form, there is a trend to follow country-specific practices, including information that is not consistent with the WHO standard form. A few countries usually provide details when the information submitted by the applicant does not satisfy the certifying authority in all aspects of the product's manufacture.

For data of administrative nature, the vast majority comply with providing the address, telephone number, name of the authorized person, and date of CPP issue. Few of them include fax numbers, and some others do not provide a specific expiration date.

CONCLUSION

This study is a broad characterization of the practices and requirements in the region of the National Regulatory Authorities of the countries of the Americas regarding the use of the CPP. The information gathered is valuable to evaluate and improve the regulatory systems according to the current demands and allows us to analyze the relevance of the current practices. Although this is not the first study conducted in the region, it has been the most extensive, the result of joint work between the industry and the NRAs, which provides additional value in the approach and in identifying the aspects to be improved.

The data included in the report may be used as a reference to evaluate the requirements applied by the NRAs in the region from a health perspective and, if appropriate, to identify opportunities for updating regulatory systems towards a more timely access to medicines and more unified approaches on such requirements. Therefore, formalizing training on the subject is an evident benefit.

This evaluation and the search for alternatives to eliminate or mitigate the time gap between global and Latin American submissions can positively impact the management activities of the industry and the NRA when reducing their administrative burden. The adequate outline of the CPP requirements following the national regulatory frameworks and the identification of the health value attributed to it by the NRA is expected to provide ideas on how to comply with drug standards in terms of safety, efficacy, and quality without delaying, in some cases, the availability of treatments.

There is an opportunity in the region to discuss the health value of the CPP in the NRAs processes. The data in this mapping can help identify points for improvement and, in that regard, pave the way for the adoption of more unified and efficient regulatory approaches. The time of publication of this report is in line with the discussions at the WHO on the revision of its Scheme, indicating a particularly important and timely circumstance for this consideration.

ANNEX I

Study participants

COUNTRY	NATIONAL REGULATORY AUTHORITY	INDUSTRY ASSOCIATION
Argentina	Agencia Nacional de Medicamentos, Alimentos y Tecnología Médica (National Administration of Drugs, Foods and Medical Devices) (ANMAT)	Cámara Argentina de Especialidades Medicinales (Argentine Chamber of Medical Specialties) (CAEME)
Barbados	Ministry of Health and Wellness - Barbados Drug Service	
Belize	Ministry of Health	
Bolivia	Agencia Estatal de Medicamentos y Tecnologías en Salud (State Agency for Drugs and Health Technologies) (AGEMED)	Bayer Boliviana Ltda.
Brazil	Agencia Nacional de Vigilancia Sanitaria (Brazilian Health Regulatory Agency) (ANVISA)	Associação da Indústria Farmacêutica de Pesquisa (Pharmaceutical Research Industry Association) (INTERFARMA)
Canada	Health Canada (HC)	
The Caribbean	Caribbean Regulatory System (CRS)	
Chile	Instituto de Salud Pública (Institute of Public Health) (ISP)	
Colombia	Instituto Nacional de Vigilancia de Medicamentos y Alimentos (National Institute of Food and Drug Monitoring) (INVIMA)	Asociación de Laboratorios Farmacéuticos de Investigación y Desarrollo (Association of Pharmaceutical Research and Development Laboratories) (AFIDRO)
Costa Rica	Dirección de Regulación de Productos de Interés Sanitario (Directorate for the Regulation of Products of Health Interest)	Federación Centroamericana de Laboratorios Farmacéuticos (Central American Federation of Pharmaceutical Laboratories) (regional chapter of the IFPMA) (FEDEFARMA)
Cuba	Centro para el Control Estatal de Medicamentos, Equipos y Dispositivos Médicos (Centre for State Control of Medicines and Medical Devices) (CECMED)	
Ecuador	Agencia Nacional de Regulación, Control y Vigilancia Sanitaria (Regulatory Control and Surveillance National Agency) (ARCSA)	Industria Farmacéutica de Investigación (Research and Innovation Pharmaceutical Industry Corporation) (IFI)
El Salvador	Dirección Nacional de Medicamentos (National Directorate of Medicines)	Federación Centroamericana de Laboratorios Farmacéuticos (Central American Federation of Pharmaceutical Laboratories) (regional chapter of the IFPMA) (FEDEFARMA)

COUNTRY	NATIONAL REGULATORY AUTHORITY	INDUSTRY ASSOCIATION
United States	Food and Drug Administration (FDA)	
Guatemala	Departamento de Regulación y Control de Productos Farmacéuticos y Afines (Department of Regulation and Control of Pharmaceutical and Related Products)	Federación Centroamericana de Laboratorios Farmacéuticos (Central American Federation of Pharmaceutical Laboratories) (regional chapter of the IFPMA) (FEDEFARMA)
Haiti	Direction de la Pharmacie, du Médicament et de la Médecine Traditionnelle du Ministère de la Santé Publique et de la Population (Directorate of Pharmacy, Medicines and Traditional Medicine of the Ministry of Public Health and Population)	
Honduras	Agencia de Regulación Sanitaria (Sanitary Regulation Agency) (ARSA)	Federación Centroamericana de Laboratorios Farmacéuticos (Central American Federation of Pharmaceutical Laboratories) (regional chapter of the IFPMA) (FEDEFARMA)
Jamaica	Ministry of Health	Roche Servicios S. A.
Mexico	Comisión Federal para la Protección contra Riesgos Sanitarios (Federal Commission for Protection against Sanitary Risk) (COFEPRIS)	Asociación Mexicana de Industrias de Investigación Farmacéutica (Mexican Association of Pharmaceutical Research Industries) (AMIIF)
Nicaragua		Bayer S. A.
Panama	Dirección Nacional de Farmacia y Drogas (National Directorate of Pharmacy and Drugs)	Federación Centroamericana de Laboratorios Farmacéuticos (Central American Federation of Pharmaceutical Laboratories) (regional chapter of the IFPMA) (FEDEFARMA)
Paraguay		Bayer S. A.
Peru	Dirección General de Medicamentos, Insumos y Drogas (General Directorate of Medicines, Supplies and Drugs) (DIGEMID)	Asociación Nacional de Laboratorios Farmacéuticos (National Association of Pharmaceutical Laboratories) (ALAFARPE)
Dominican Republic		Federación Centroamericana de Laboratorios Farmacéuticos (Central American Federation of Pharmaceutical Laboratories) (regional chapter of the IFPMA) (FEDEFARMA)
Suriname	Ministry of Health	
Trinidad and Tobago	Chemistry/Food and Drugs Division	Roche Servicios S. A.
Uruguay	Ministry of Public Health	Cámara de Especialidades Farmacéuticas y Afines (Chamber of Pharmaceutical Specialties and Related Products) (CEFA)
Venezuela	Instituto Nacional de Higiene “Rafael Rangel” (National Institute of Hygiene “Rafael Rangel”)	
27 countries	**24 NRAs** **1 regulatory system**	**18 responses from countries provided by 8 pharmaceutical associations and 2 companies**

ANNEX II

Composition of the survey

	TOPICS	QUESTIONS
1	Submission of applications for new drugs/new pharmaceutical products	16
2	Submission of renewal applications	3
3	Submission of post-approval changes/variations	4
4	Form/content of the CPP document	5
5	NRA assessment of the CPP	6
6	Assessment of the previous registration in the country of origin	3
7	Effects of registration/marketing authorization cancelation or suspension in the CPP-issuing country	4
8	CPP and marketing status of the product	4
9	Other relevant information	9
10	NRAs issuing CPP (only for NRAs issuing CPPs)	4
TOTAL: 10 topics		58

Reference documents

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- *Documento técnico de la Red PARF N.° 10 de 2013* (standard document for the registration of drugs).

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