COVID-19 Medical Device Regulatory Convergence Project (MDRC)

Mexico

2021 Report

Executive Summary

The Medical Devices Regulatory Convergence Project for COVID-19 (MDRC) aims to increase the predictability of the regulatory ecosystems of medical devices, through the development of capacities focused on achieving the alignment of national regulations with international standards and references, starting from the systematic implementation of Good Regulatory Practices (GRP) in the updating and development process of regulations.

Following the signing of the Letter of Intent, the project's areas of focus were defined, ranging from capacity-building on GRP, identifying the international obligations of public institutions such as COFEPRIS and the Pharmacopoeia of the Mexican United States, with a view to incorporating them into their quality management systems, to addressing specific technical and procedural issues.

Among other activities, preparation trainings and workshops have been carried out for the recognition of certificates issued based on the outcomes of the Medical Devices Single Audit Program (MDSAP), committed to the USMCA; a webinar on GRP was developed; a series of virtual seminars on the use of international standards and references, and conformity assessment are under way to promote its use and the active participation of all relevant actors in the implementation of the regulations; and the action plan for 2022 was drawn up. Among the objectives of the plan is the collection of inputs and capacity-building that will eventually enable the incorporation of COFEPRIS into the International Medical Devices Regulators Forum (IMDRF) and the MDSAP.

Detailed information on progress to date can be found in the body of this report.

Introduction

In order to expand the predictability of regulatory ecosystems for medical devices and build capacities in efforts to combat and recover from the COVID-19 pandemic, the United States Agency for International Development (USAID) and the American National Standards Institute (ANSI), in collaboration with the Advanced Medical Technology Association (AdvaMed) and the Inter-American Coalition for Regulatory

Convergence in the Medical Technology Sector (IACRC-MTS), work together with the Mexican Federal Commission for the Protection against Sanitary Risks (COFEPRIS) and the Pharmacopoeia of the United Mexican States (FEUM) in the implementation of the USAID Standards Alliance COVID-19 Medical Device Regulatory Convergence Project (MDRC). The MDRC facilitates information exchange, provides training and related resources in order to support the alignment of the Mexican national regulatory framework and technical regulations and standards with international standards.

The project, in addition to the collaborative initiatives between the United States and Mexico within the framework of the High-Level Economic Dialogue, seeks to strengthen and accelerate access to medical devices through technical cooperation focused on the harmonization of the Mexican regulatory system. In this regard, it is given priority and urgency in the context of the COVID-19 pandemic to promote the production and distribution of medical devices to prevent and treat the virus. The MDRC is also structured to support a broader and long-term scope through the application of regulatory convergence for the implementation of firm mechanisms that improve the processes of medical device authorization, control, and surveillance through the development of capacities of the participating institutions, in both the regulatory and operational fields. Accordingly, the transparency of the regulatory processes is increased and technical barriers to trade are reduced; thus, facilitating access to market and the import and export of supplies in the sector.

Commitments

The MDRC contemplates developing, over a three-year period, collaborative activities, which have been formalized through a Letter of Intent in which the modalities of collaboration are agreed upon. The objectives achieved in the carried-out activities shall be reflected in an annual report.

2021 Activities

Letter of Intent

On August 31, COFEPRIS, USAID, the IACRC-MTS signed a "Letter of Intent" that ANSI signed on September 9, 2021. The commitment lays the foundation for joint work within the framework of medical technologies, including medical devices, *in vitro* diagnostic reagents, and digital technologies for health, with a view to encouraging and facilitating mutual contacts, information exchanges, training, and cooperation

between government agencies, health institutions, health professionals, specialists, and private institutions.

This bond specifies the following modalities of cooperation:

- To develop actions in the scientific and technical field for regulatory strengthening.
- To promote the competitiveness of the industry, through the optimization of processes, practices, and regulations, at the level of best practices and international standards.
- To promote the regulatory convergence of Medical Devices, based on Good Regulatory Practices (GRP) and the reference to internationally recognized standards.
- To disseminate technical, scientific, and ethical knowledge that supports both industrial development and regulatory policies.
- To establish specific projects aimed at promoting the use of International Standards for regulatory purposes.

Training on Good Regulatory Practices and their Implementation in the Medical Device Sector

On October 27, November 10, 17 and 24, 2021, COFEPRIS and the Standards Alliance (USAID, ANSI, and IACRC-MTS), held a series of trainings on Good Regulatory Practices and their Implementation in the Medical Device Sector.

The objective of the training was to promote, through presentations, the exchange of experiences, and a discussion panel on the subject, the use of Good Regulatory Practices in the process of implementing international standards for regulatory purposes.

The event was presented as a virtual seminar consisting of four sessions of two hours each, including generalities and international commitments, the Good Regulatory Practices in the international and national field of medical products, as well as the regulatory processes in Mexico, challenges and opportunities of the regulatory convergence in the medical device sector.

There was interaction that advanced the project objectives by representatives of government, the private sector and international organizations, including the World

Health Organization, the Pan American Health Organization, the Deputy Secretariat of Foreign Trade, the General Directorate of Standards, the Pharmacopeia of the United Mexican States (FEUM) and COFEPRIS.

The first session dealt with the generalities of Good Regulatory Practices, their consideration and observance within various Trade Agreements. The National Regulatory Authorities of Bolivia, Brazil, Colombia, El Salvador and Honduras participated, as well as more than 50 COFEPRIS employees, as well as representatives of more than 180 companies from 10 countries, for a total of 264 attendees, of which 194 were women and 70 men. The attendees learned about the relevance of GRP in the daily work, not only to generate more efficient regulatory processes, but also, and in a highly relevant way, to guarantee compliance with their legal obligations in this context.

The second session focused on Good Regulatory Practices applied to the regulation of medical products, through the participation of the World Health Organization, and the review of the Regulatory Process in Mexico, by the General Directorate of Standards and COFEPRIS itself. In this session, regulators from Bolivia, Colombia, El Salvador, Honduras and Peru participated, in addition to 99 companies located in 8 countries of the continent, for a total of 183 participants, of which 130 were women and 53 men. In the presentations, the relevance of GRP in the health regulatory field was established, as well as the importance of knowing the local processes that guarantee that the actions relating to regulation are also carried out in compliance with local legal obligations.

During the third session, the knowledge of the development process of regulations applicable to medical devices was deepened, both at the level of regulations, as well as in Mexican Official Standards (technical regulations, NOM) and the publications of the FEUM. This session identified the need to implement improvements in the operational processes to develop and update technical regulations of COFEPRIS and FEUM, considering the binding commitments established in the international agreements to which Mexico is a party. Regulators from Bolivia, Colombia, El Salvador, Honduras and Mexico participated, with more than 50 participants, as well as representatives of 95 companies from 8 countries, for a total of 165, of which 118 were women, 46 men and one without gender declaration.

In the fourth and final session, a discussion panel was held on the challenges and opportunities of Medical Devices Regulatory Convergence, in light of GRP, in which the relevant stakeholders from the government and private sector in Mexico participated, both at the government level and in the private sector. All panelists agreed on the advantages of convergence, not only to facilitate access to medical

devices, but also to generate capacities that benefit institutions and promote compliance with legal obligations, both locally and internationally by the competent stakeholders, as appropriate to their respective attributions, assuming the co-responsibility of all the sectors involved. For this session, there was the participation of regulators from Colombia, Honduras, Spain and Mexico with more than 50 participants, in addition to the representation of the Pan American Health Organization, 83 representatives of the industry, for a total of 153 participants, of which 104 were women and 48 men, plus one without gender declaration.

The event was broadcasted via web in Spanish and English simultaneously, with the assistance of interpreters, together with the materials, including recordings, which were made available to the public in both languages. These digital materials are available online on the IACRC-MTS website: "Good Regulatory Practices and their Implementation in the Medical Device Sector in Mexico"[1]

Regular meetings

In order to follow up on the implementation of the Project, recurrent meetings between COFEPRIS and the IACRC-MTS, as a conduit of the Standards Alliance, are held on a weekly basis as of July 16, except for sporadic suspensions when incompatibilities of the agendas require it.

Other activities

In the context of the MDRC, COFEPRIS has also been invited to and participated in the various events held under the coordination of other regulatory agencies:

In June (2, 10, 17 and 24) of 2021, a series of virtual seminars on medical devices organized by the FDA and the IACRC-MTS was held, which aimed to address the International Standard ISO 13485 on Quality Management Systems, the Medical Device Single Audit Program (MDSAP) and the use of MDSAP products for regulatory purposes; experiences of the National Health Surveillance Agency (ANVISA) of Brazil and the National Administration of Drugs, Foods and Medical Devices (ANMAT) of Argentina were shared. The joint participation of the industry was promoted during the first three sessions and the fourth and last session was reserved for the exclusive access of regulatory agencies, with the intention of strengthening the exchange of experiences and fostering regulatory convergence. Among other guests, the

[1] https://www.interamericancoalition-medtech.org/regulatory-convergence/training-and-capacity-building-resources/policy-training/serie-de-webinarios-sobre-buenas-practicas-regulatorias-y-su-implementacion-en-el-sector-de-dispositivos-medicos-en-mexico/?lang=es

attendance of the Institute of Public Health (ISP) of Chile, the National Institute for Drug and Food Surveillance (INVIMA) of Colombia and the General Directorate of Medicines, Supplies and Drugs (DIGEMID) of Peru was appreciated, nurturing the regional perspective. ISO 13485 and MDSAP are relevant topics for COFEPRIS and MDRC regarding compliance with USMCA obligations.

On November 3, the United States Food and Drug Administration (FDA) and COFEPRIS held a Technical Meeting where the implementation of ISO 13485 was discussed and on November 4, a Workshop on the Medical Device Single Audit Program (MDSAP) was held specifically aimed to COFEPRIS personnel involved in Medical Device processes. It was an event limited to the two regulatory agencies, with the benefit of simultaneous interpretation under the sponsorship of the MDRC, in order to mitigate the obstacle that in its extent represents the difference of language. The conditions of the pandemic forced to distribute the participation in face-to-face mode and virtual rooms, but that did not limit the clear interaction of more than 34 officers, technicians and managers. The meeting and workshop provided more specific guidance on the use of audit models and clarified doubts about the implementation of the Standard and the Audit Program. These sessions have been of great relevance as part of the assimilation process of COFEPRIS with respect to international standards and co-operation schemes, such as the results of the audits carried out under the MDSAP program, to comply with the commitment established in this regard, in the United States, Mexico and Canada Trade Agreement.

On November 30, the World Bank offered a Webinar on Commitments with External Stakeholders. Some of the topics discussed during this meeting were the benefits of Good Regulatory Practices (GRP) and their implication in the Health Sector, from the perspective of the Bank; as well as the panorama of the National Health Surveillance Agency (ANVISA) of Brazil on the adoption of GRPs and the experience of inter-institutional collaboration in Colombia for the implementation of GRPs. COFEPRIS increased awareness of the benefits and alternatives to implement GRPs.

Likewise, on December 7, the series of webinars on the Use of Voluntary Consensus Standards, organized by the FDA in coordination with the IACRC-MTS began. The FDA shared its experience in the development and application of consensual standards as a tool for better regulatory decision-making. This was presented with a focus on the FDA CDRH Standards and Conformity Assessment Program. The event had the participation of COFEPRIS' representatives .

It can be pointed out that parallel to the development of the MDRC, COFEPRIS carries out multiple activities in the field of Medical Devices that, although not precisely

circumscribed within the framework of the MDRC, share a common objective: regulatory convergence in the field of medical devices.

The international agenda of the COFEPRIS is aimed at strengthening its technical, operational and regulatory capacity, and as part of the international cooperation strategy, the participation of the Federal Commission has also been promoted in other initiatives, regulatory forums, collaboration mechanisms, working groups, training programs, specific projects, signing of collaboration agreements and equivalence recognition agreements, which represent an important platform to facilitate the exercise of the powers of the institution, through: access to successful experiences of countries in the field of health regulation; provide updated technical information to support the operation and analysis; access to relevant technical information that contributes to decision making; standardize criteria that lead to regulatory convergence and efficient processes.

The collaborative relationship with the FDA was strengthened, prioritizing, among other issues, medical devices. Along these lines, the FDA has offered its willingness to accompany the COFEPRIS in its process of accession to MDSAP, in principle, through the prior review of the application form, in order to obtain greater certainty in the possibility of entry.

Participation in meetings and forums of the World Health Organization and the Pan American Health Organization was made possible through MDRC support. This work complements the development of regulatory convergence of Medical Devices. Participation gives COFEPRIS visibility to the work performed: by the Working Group for the Global Regulatory Model; updates or conferences on standardized nomenclatures which recommend guiding principles, harmonized definitions and specify the attributes of an effective and efficient, and internationally acceptable regulation.

High-Level Economic Dialogue

The MDRC has been strongly driven by its focus within the topics of the High-Level Economic Dialogue (HLED) between Mexico and the United States, as a trade facilitation partnership to improve access to COVID-19-related medical devices.

Visualizing then the opportunity to gradually overcome the pandemic, axes of joint reconstruction between both nations were proposed, complementing bilateral efforts on certain fields of common interest, in order to help face the present challenges and guarantee prosperity of the society. Along these lines, a consultation was carried out

with the private sector, citizens and government agencies to contribute to the Dialogue to promote a climate of inclusion, obtain diverse points of view and ensure transparency in decision making.

Thus, under pillar number 1: Rebuilding Together, the regulatory convergence of medical devices was proposed.

Plans

On January 20 and 27, COFEPRIS plans to participate in the webinar "Unique Device Identification (UDI)" developed by the FDA, in coordination with the IACRC-MTS, in which an overview of the requirements related to the UDI and the perspective and experience of the Brazilian, Colombian, Ecuadorian and U.S. authorities in its implementation will be presented.

The continued participation of attendees and speakers in the subsequent sessions of the series of webinars on the utilization of international standards and conformity assessment is planned, which will be delivered by the FDA together with different regional regulatory stakeholders, to be carried out on March 3, 10 and 17, 2022.

There is a desire from COFEPRIS to obtain the consent to participate as guest observers in working groups of the International Medical Device Regulators Forum (IMDRF), as well as in the open events that take place during the meetings to be held in 2022.

Work is being done on the compendium of requirements and the completion of the MDSAP membership application form. Along these lines, it was proposed to hold talks with the National Regulatory Authorities that are already part of this mechanism . This was an opportunity to answer questions and gather more information about the tool, contributing to the best decision making on its implementation . To complement this work, a dialogue was held on November 19th, with the National Administration of Drugs, Foods and Medical Devices (ANMAT) of Argentina, who shared its experience in the process and in the use and benefits of the Program in its capacity as an Affiliate Member . In addition , a conversation is scheduled to begin with the National Health Surveillance Agency (ANVISA) of Brazil, tentatively on January 25, 2022 to further contribute to the MDSAP membership application..

There are plans to review the current technical standards in order to identify opportunities for updating and improvement, for example, NOM-137-SSA1-2008, Labeling of medical devices, which aims to communicate information to users about

the specifications that labeling should have for medical devices of national or foreign origin that are marketed or destined for the domestic market.

Strategies will be analyzed to strengthen adherence to good regulatory practices at both COFEPRIS and FEUM and better address compliance with the legal obligations established in international treaties.

Analyses and work are ongoing to modify the criteria for the recognition of certain processes and technical evaluations for quality management systems of manufacturers in accordance with the provisions of the United States, Mexico and Canada Agreement (USMCA). This is being achieved by considering references such as ISO 13485 and MDSAP.

Priorities identified

Specific topics of interest were identified by COFEPRIS throughout internal consultations and by the MDRC team via consultations with the stakeholders in the private sector:

COFEPRIS

Training actions, information exchanges and training resources regarding:

- Learning and exchanging of experiences regarding IMDRF
- Continue with ISO and MDSAP training
- Information on new technologies
- Software as a medical device
- Personalized medical devices
- Medical device reprocessing
- State-of-the-art systems for adverse event reports

IACRC-MTS

- Update of the MEXICAN OFFICIAL STANDARD NOM-137-SSA1-2008, Labeling of Medical Devices.
- Alignment with international standards regarding scope and terms.
- Alignment of the Advertising Regulation with international best practices.
- Development of the requirements for obtaining health records of medical devices, aligned with international standards, and published in the relevant regulatory instrument.
- Development of the regulation for Emergency Use Authorizations for Medical Devices with pre- and post-market scope, aligned with international standards.
- Implementation of a Good Regulatory Practices Policy in the Quality Management System of COFEPRIS and FEUM, in accordance with the

recommendations generated by WHO and in compliance with the commitments established between the Government of Mexico and the WTO, the OECD, and the USMCA.
- Alignment with international references on the use of Accelerated Stability Studies for expiration time assignment

Conclusions of the MDRC during 2021 operation

The MDRC contributes to the strengthening of the National Regulatory Agency, supports the building of trust between Health Agencies and identifies mechanisms that avoid duplication of efforts to optimize processes, reduce costs and timely offer quality, safety, effectiveness and performance supplies guaranteed to the population.

It is expected that the project will continue to contribute to the achievement of a greater degree of regulatory convergence with best international practices by COFEPRIS for medical devices.

Continuity is given to the Medical Devices Regulatory Convergence (MDRC) and Medical Technology for COVID-19 Project in the face of evidence that a better regulatory performance with harmonized requirements, control and surveillance processes is the way to avoid technical barriers to trade, facilitating and streamlining access to supplies for the timely treatment of patients.

Even though COVID-19 motivates the implementation of the MDRC, the results of this project go beyond mitigating of the effects of the pandemic, since it aspires to strengthen with a firm regulatory model based on the recognition of international equivalent best processes, optimizing resources and management times.

There has been broad agreement in the standards, references and mechanisms suggested through the MDRC with those that COFEPRIS already contemplated in its convergence plan, which in turn highlights the guidelines proposed by the IMDRF and unified programs such as the MDSAP. It is also serving to address the binding commitments derived from trade agreements such as the USMCA, TIPAT, Pacific Alliance, among others.

Additional specific areas of opportunity, as described below, have been identified throughout the working sessions. These topics are being addressed under various activities included in the action plan.

- Disaggregation of data for the medical device sector and development of metrics to measure the performance and progress of regulatory convergence.
- Development of actions aimed at improving performance in terms of good regulatory practices, including the development of regulatory impact analysis during the development or updating of regulatory instruments (regulations, NOMs, FEUM).
- Transfer of technology: Explore of computer tools for the management and dissemination of data.
- Increasing evidence for transparency.
- Improvement of the communication channels with the regulated industry.
- Optimization of management times for the attention of formalities.
- Promotion of the use of international references such as those produced by IMDRF and MDSAP, reinforced by actions for incorporation as a member of them.
- Greater interrelation of governmental organizations, highlighting the FEUM and SE (CONAMER, DGN).
- Address language gaps.
- Strengthening of the compliance with other international commitments (USMCA, CPTPP, Pacific Alliance, WTO).