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Perspectives for licensing vaccines in Mexico

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**A B S T R A C T**

Vaccine products represent one of the most successful public health measures to this day. This has been reflected during the current COVID-19 pandemic where more than 4.87 billion people have received at least one vaccine dose. In Latin America, Mexico occupies the second position in terms of the number of vaccinated people with 83.97 million people receiving at least a single dose. As in other countries, regulatory approval in Mexico is one of the key aspects that influences the public access to vaccines. This creates an active interplay between regulatory authorities establishing a regulatory framework to assure the quality, safety and efficacy of the vaccines, and applicants fulfilling this information. Mexico is a member of the International Council for Harmonisation (ICH) and it has adopted the Common Technical Document (CTD) for providing this information. This is particularly useful for vaccines developed abroad where it is expected to speed the evaluation of the new product. The Secretariat of Health of Mexico (SALUD) has published guidelines and laws or regulations related to GMP, labeling, stability, clinical trials, biocomparability and pharmacovigilance for drug products including vaccines which are classified as biological products. SALUD has also established guidelines and international homologating agreements to facilitate the application process for vaccine approval. Nevertheless, technical and scientific information and administrative processes for vaccine approval might be relatively concealed. Therefore, we aim to enable researchers and manufacturers in Mexico and overseas to better understand these requirements. To our knowledge, this is the most up-to-date and comprehensive attempt to present this information, also including information for COVID-19 vaccines. Here we describe the current requirements and processes by COFEPRIS, the national regulatory agency, for vaccine licensing and for emergency use authorization for COVID-19 vaccines in Mexico.

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1. Introduction

Vaccines are biological preparations destined to generate immunity against a certain disease through the production of antibodies (and/or T cell responses) to eliminate, prevent or control a pathological state [1]. Vaccines are also considered one of the most successful and cost-effective public health measures to combat disease [2].

Globally, the sales of vaccines are considerable. According to the World Health Organization (WHO), vaccines sales were estimated in 5.5 billion doses representing 33 billion USD in 2019 [3]. According to the same organization, polio, diphtheria, tetanus and measles vaccines were the most sold by volume. In a similar analysis, the market in Mexico for systemic anti-infectives represented 1.174 billion USD in the same year 2019 [4]. In terms of COVID-19 vaccines, 10.35 billion doses have been administered globally and Mexico has acquired 243,930,000 doses since the beginning of the pandemic [5,6].

National regulatory agencies and international organizations have adopted a pathway for the approval of vaccine products including evaluations at the level of quality, non-clinical and clinical. The World Health organization (WHO) and the regulatory agencies for Europe (EMA) and the United States (FDA) regularly release guidelines related to quality, clinical and non-clinical topics [7,8,9].

The International Conference for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) publishes relevant guidelines harmonized between the USA, Japan and the European Union [10]. In 2021, Mexico became the first Spanish-speaking country in the Americas to become a member of the ICH, which is considered one of the top global forums in terms of harmonization of technical requirements for the registration of medicaments. This potentially would allow Mexico to be considered a strategic and competitive destiny to perform clinical trials, eliminating the necessity of duplicating R&D work performed...
abroad and allowing the performance of this work in the Mexican territory with homologated procedures from the other ICH members [11]. The ICH has established the Common Technical Document (CTD). The CTD organizes the technical information to be submitted for approval in five modules. Module 1 is region specific, and Modules 2, 3, 4 and 5 are meant to be common for all regions. Module 1 encompasses administrative regional information. Module 2 summarizes all modules. Module 3 comprises quality attributes. Module 4 and 5 include non-clinical and clinical reports, respectively.

In July 2003, the CTD became the mandatory format for new drug applications in the European Union and Japan, and it is strongly recommended for new drug applications by the USA national regulatory agency, the FDA [12]. The CTD has also been adopted by other economical partners of Mexico such as Canada and Brazil [13,14].

As of January 2021, the WHO established the CTD as mandatory for the prequalification of vaccines. The prequalification of vaccines is a service provided to UNICEF and other UN agencies to ensure that the vaccines used in immunization programs are safe and effective [15]. In addition, the Pan American Health Organization (PAHO) provides guidance for industry for the preparation of submissions according to the format presented in the CTD [16].

In Mexico, the current regulatory framework classify vaccines as biological products and biotechnological medicaments. Biotechnological products are defined as the preparation coming from cells, tissues or organisms, with which vaccines, allergens, blood and biotechnological products are prepared [1]. Biotechnological medicaments are defined as all substance that has been produced by molecular biotechnology conferring a therapeutic, preventive or rehabilitating effect [17]. Relatively new vaccine platforms such as adenoviral vectors can be classified as biotechnological medicaments since they are constructed using molecular biotechnology and confer a preventive effect.

The COFEPRIS (Federal Commission for Protection against Sanitary Risks) is the national regulatory agency responsible for regulating vaccine products in Mexico. COFEPRIS issues guidelines for vaccine licensing, including other steps of the product life cycle such as manufacturing, commercialization, advertising, distribution, importation and exportation. COFEPRIS is a decentralized body of the Secretariat of Health (SALUD) and it was created in 2001 [18,19].

In terms of COVID-19 vaccines, Mexico has approved numerous vaccines under an emergency use authorization (EUA) scheme. The requirements and processes for EUA have the aim of expediting the availability of COVID-19 vaccines in the Mexican territory while focusing on quality, efficacy and safety.

In this review, we describe the regulatory pathways in Mexico for licensing vaccines by COFEPRIS also addressing the required technical and scientific information to be submitted for evaluation. We aim to enable national and international researchers and manufacturers to better comprehend these requirements. To our knowledge, this is the most up-to-date and comprehensive attempt to present this information. We also expand this information to the EUA of COVID-19 vaccines due to the relevance of the topic.

### 2. Evaluation procedures of vaccines in Mexico

The evaluation procedures for vaccine licensing by COFEPRIS are in agreement with different regulatory agencies and international organizations, as described in an Agreement published in January 2020 in the Official Journal of the Federation [20]. The COFEPRIS will require the following information in a CTD format having been previously evaluated by the New Molecules Committee.

- **a. Identity and purity of the components according to the Pharmacopoeia of the Mexican United States (FEUM by its Spanish acronym)**
- **b. Stability of the finished product according to the corresponding law NOM-073-SSA1-2015**
- **c. Therapeutic efficacy and safety**
- **d. Prescribing information**
- **e. Product labeling and instructive of use, also primary and secondary packaging specifications in accordance to law NOM-072-SSA1-2012**
- **f. Good Manufacturing Practices (GMP) certificate according to the current law NOM-059-SSA1-2015**
- **g. Owner of the existing patent**

The New Molecules Committee is an auxiliary entity of COFEPRIS for consulting and emitting technical opinions regarding medicaments containing new molecules or vaccines [21]. The activities of this committee are similar to the ones from the Vaccines and Related Biological Products Advisory Committee (VRBPAC) of the FDA [22] and the Scientific Advisory Group on Vaccines (SAG-V) of the EMA [23].

By this Agreement, the evaluation process by COFEPRIS is homologated to the procedures of the Swiss Agency for Therapeutic Products-Swissmedic, the European Commission, the Food & Drug Administration of the USA (FDA), the Health Ministry of Canada, the Therapeutic Goods Administration of Australia (TGA) and the PAHO/WHO guidelines, among others.

According to the COFEPRIS, the complete evaluation process usually lasts 240 calendar days, excluding the New Molecules Committee evaluation time that usually lasts 4 weeks [24]. Nevertheless, the process, as per the homologation with the WHO prequalification scheme, usually lasts 60 working days. After the COFEPRIS evaluation of the submitted information, the COFEPRIS can ask for more technical or administrative information if there is lacking or inconsistent information. The overall process for COFEPRIS evaluation is shown in Fig. 1.

### 3. Regulations of vaccines in Mexico

There are laws, guidelines and agreements in Mexico that encompass the steps of the life-cycle of the vaccine product. These are related to non-clinical and clinical research, manufacturing (GMP), commercialization and pharmacovigilance. Most of these laws are general for medicaments and biological products. These are summarized in Table 1.

Considering the vaccine development cycle, the NOM-062-ZOO-1999 would be relevant to follow when conducting animal studies, while the NOM-012-SSA3-2012 would be relevant when conducting clinical studies (phases 1–3). Furthermore, the NOM-220-SSA1-2012 comprises information related to pharmacovigilance (phase 4).

Mexico has a specific law for vaccines, the NOM-036-SSA2-2012. The objective of this law is to homologate the criteria and procedures for the application, conservation and handling of vaccines, toxoids, blood products and immunoglobulins for human use. The law establishes recognized definitions for key terms in vaccination, which can be useful to better understand Mexican accepted terminology. The law also describes doses, pharmaceutical forms and demographical profiles of currently distributed vaccines in Mexico [25].

There is also an agreement for the modifications of the registry conditions of vaccines. This agreement establishes that the regis-
tration holders have to demonstrate that the modifications done to the vaccine products do not modify their quality, safety and efficacy. The procedures and the required information are described throughout the document (Table 1, “Guideline for the Modification to the registry conditions of vaccines”).

4. Pharmacopoeia of the united states of Mexico

The Pharmacopoeia of the United States of Mexico (FEUM as abbreviated in Spanish) is the document established by the General Law of Health which describes de general methods of analysis and requirements about the identity, purity and quality of vaccines, biological products and medicaments to assure its safety, efficacy and functionality [26,27]. The content of the FEUM should be considered during the CTD elaboration for COFEPRIS submission as previously indicated. The FEUM describes information for several vaccines, including information for different combinations, pharmaceutical forms and adjuvants. The content of the FEUM related to vaccines is summarized in Fig. 2.

Fig. 1. Overall process for the approval of vaccines by COFEPRIS.

Fig. 2. Summary of the vaccine information contained in the FEUM version 13.0 [27].
Table 1
Regulatory framework that support the development and commercialization of vaccines in Mexico. NOM stands for Norma Oficial Mexicana, which translates to Official Mexican Standard.

| Regulation | Title | Source |
|------------|-------|--------|
| NOM-176-SSA1-1998 | Sanitary requirements for the manufacturers, distributors and providers of drug substances used in the elaboration of medicaments for human use | https://www.farmacopea.org.mx/Repositorio/legislacionFiles/NOM-176ReqSan17dic01.pdf |
| NOM-062-ZOO-1999 | Technical specifications for the production, care and use of laboratory animals | https://www.gob.mx/cms/uploads/attachment/file/203498/NOM-062-ZOO-1999_220801.pdf |
| NOM-012-SSA3-2012 | Establishing the criteria for the execution of health-related research projects in humans | https://doi.gob.mx/nota_detalle.php?codigo = 5284148&fecha = 04/01/2013 |
| NOM-059-SSA1-2013 | Good Manufacturing Practices of medications | https://doi.gob.mx/nota_detalle.php?codigo = 5424575&fecha = 05/02/2016 |
| NOM-059-SSA1-2013 | Good Manufacturing Practices of drug substances | https://www.dof.gob.mx/nota_detalle.php?codigo = 5307888&fecha = 25/06/2013 |
| NOM-072-SSA1-2012 | Labeling of drug and herbal products | https://www.dof.gob.mx/nota_detalle.php?codigo = 5278341&fecha = 21/11/2012 |
| NOM-073-SSA1-2005 | Stability of drug substances and medicaments | https://www.dof.gob.mx/nota_detalle.php?codigo = 5440183 &fecha = 19/07/2017 |
| NOM-220-SSA1-2012 | Installation and operation in pharmaceutical | https://www.dof.gob.mx/nota_detalle.php?codigo = 5490830&fecha = 28/09/2012 |
| NOM-036-SSA2-2012 | Prevention and control of diseases. Application of vaccines, toxoids, fabotherapeutic agents (sera) and immunoglobulins in humans | https://www.gob.mx/cms/uploads/attachment/file/525238/Guía_de_Modificaciones_de_Vacunas.pdf |
| Guideline | Modification to the registry conditions of vaccines | https://www.dof.gob.mx/nota_detalle.php?codigo = 5352631&fecha = 16/07/2014 |

5. Common technical document (CTD)

Mexico has adopted the Common Technical Document (CTD) format for providing technical information for COFEPRIS evaluation. The Government of Mexico has published guidelines concerning the content of the CTD. This content is harmonized with other ICH member states and recognized international entities [20]. The content of the CTD comprises (1) Administrative-legal information, (2) Summary of the sections, (3) Quality attributes, (4) Pre-clinical and (5) Clinical evidence. A summary of the content of the CTD sections is summarized in Table 2.

6. Emergency use authorization of covid-19 vaccines in Mexico

To this date, Mexico has approved different COVID-19 vaccines under an emergency use authorization (EUA) scheme. The vaccines comprise different technologies such as adenoviral vectors, mRNA, inactivated SARS-CoV-2 and protein vaccines. These vaccines and their characteristics are described in Table 3.

An official guideline has been established regarding the authorization for the manufacturing, importation and commercialization of products that contribute to the eradication and mitigation of COVID-19, including vaccines [28]. It is described in the guideline that the technical requirements for the authorization are according to the CTD. These requirements are summarized in Table 4. GMP compliance and a prior evaluation by the New Molecules Committee is required, as well as a legal representation in Mexico.

As in other countries, the emergency use authorization of COVID-19 vaccines in Mexico have strongly relied on the results of an interim efficacy analysis during the phase 3 clinical trials, i.e., when the success criteria for efficacy has been met before the planned phase 3 clinical trial end date. Even though Mexico to this date has not fully licensed COVID-19 vaccines, it is expected
that a full licensing will require the more extensive phase 3 clinical results (according to the pre-specified clinical trial dates and experimental designs). According to the aforementioned official guideline, preclinical and clinical information must be submitted as summaries for EUA, which strongly contributes for expediting the vaccine evaluation process.

Table 3
COVID-19 vaccines currently approved under an emergency use authorization (EUA) scheme [29,30].

| Vaccine               | Manufacturer¹ or legal representative in Mexico² | Vaccine platform          | Clinical trial in Mexico | Doses               | Minimum age for application | Storage conditions                      |
|-----------------------|-------------------------------------------------|---------------------------|--------------------------|---------------------|-----------------------------|-----------------------------------------|
| BNT162b2              | Pfizer, Inc./BioNTech³                           | Messenger RNA             | No                       | 2                   | 12 years                    | −80 °C to −60 °C                       |
| AZD1222, Covishield   | AstraZeneca¹                                    | Non-replicating viral vector | No                       | 2                   | 18 years                    | 2 °C to 8 °C                           |
| Gam-COVID-Vac         | FSB Gamaleya National Center of Epidemiology and Microbiology of the Ministry of Health of Russia¹ | Non-replicating viral vector | No                       | 2                   | 18 years                    | −18 °C or colder                       |
| Coronavac Ad5-nCoV, Covidencia | Sinovac Life Sciences Co., Ltd¹ | Inactivated virus | No                       | 2                   | 18 years                    | 2 °C to 8 °C                           |
| BBV152 Covaxin Ad26.COV2-S | Bharat Biotech International Limited¹  | Inactivated viral vector | No                       | 2                   | 18 years                    | −25 °C to −15 °C (24 months) 2 °C to 8 °C (3 months) |
| CX-024414             | Birmex²                                         | Messenger RNA             | No                       | 2                   | 18 years                    | −25 °C to −15 °C                       |
| SARS-CoV-2 antigen    | Birmex²                                         | Inactivated Vero cells    | No                       | 2                   | 18 years                    | −2 °C to 8 °C                          |
| CIGB-66 (Abdala)      | TBD                              | Recombinant protein       | No                       | 3                   | 18 years                    | 4 °C to 8 °C                           |

Table 4
Summary of the technical information for vaccine emergency use authorization according to the ICH CTD format.

| Module | Title                      | Requirements                                                                 |
|--------|----------------------------|-----------------------------------------------------------------------------|
| 1      | Administrative-legal        | Application letter, labeling, instructive, prescribing information, market authorization, free sale certificate, patent information, New Molecules Committee outcome, GMP certificate, vaccine characteristics, legal representation in Mexico, responsible for analysis and product release in Mexico |
| 2      | Summary of CTD             | Summary of quality, pre-clinical and clinical information                     |
| 3      | CTD Quality                | Qualitative and quantitative formula, manufacturing process, quality controls involving the drug substance, additives and drug products, certificate of analysis, container closing system, stability studies, interchangeability information |

Fig. 3. Vaccine technologies for infectious diseases. Figure created with BioRender.com.
7. Challenges concerning vaccine licensing and emergency use authorization

The advancement in the development of vaccines has been reflected in the current diversity of vaccines technologies to combat infectious diseases (Fig. 3). Nevertheless, this diversity might also challenge the current legal framework for vaccine approval.

During the current COVID-19 pandemic, we saw the first licensing of an mRNA-based vaccine [31]. These vaccines are made by synthetic nucleotides usually encapsulated in liposomes. Due to the nature of these vaccines, this creates the necessity to develop and validate approved new methodology for the evaluation of quality attributes.

Other vaccine technologies might fall into overlapping regulations. Adenoviral-vectorised vaccines might fall into the category of biotechnological medicaments. The article 222 Bis of the General Law of Health defines biotechnological medicaments as all substance that has been produced by molecular biology conferring a therapeutic, preventive or rehabilitating effect [17]. There is a specific law for biotechnological medicaments concerning the general directives for the technical and scientific evaluation for this type of products, namely NOM-257-SSA1-2014 [32].

Novel routes for vaccine administration based on adenovirus or mRNA technology can also challenge the current evaluation process. This is the example of the COVID-19 vaccine of the company Vaxart, Inc., which is currently under clinical development. The vaccine is an oral administered adenoviral vector whose principal mechanism of action is the activation of specific T cell responses in the mucosa [33]. Although the approach has proved efficacious for other respiratory infectious diseases [34], these immunological features might challenge the current evaluation procedures as an evidence of strong systemic immune responses is usually required for emergency use authorization approval for COVID-19.

There are infectious diseases that might challenge the evaluation process due to their nature. There are lethal diseases such as the Nipah virus infection or the Middle East Respiratory Syndrome (MERS) which have epidemic or pandemic potential and where conventional phase 3 clinical trials might not be suitable. Perhaps a clear and sensible definition of efficacy for these cases or the inclusion of surrogates of efficacy might be worth to consider for vaccine approval.

8. Concluding remarks

The current Mexican regulatory framework and COFEPRIS evaluation process for vaccines have shown to be competent and homologated to international high standards. The emergence of new infectious diseases such as COVID-19 and the rapid development of new vaccine technologies such as mRNA-based vaccines or oral vaccines for respiratory infectious diseases might challenge the current regulatory framework. It is therefore primordial that regulation entities and vaccine developers continue communicate strongly for the successful approval of vaccines.

Author contributions
All authors listed have made a substantial, direct and intellectual contribution to the work, and they have approved its publication.

Data availability
Data will be made available on request.

Declaration of Competing Interest
The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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