

**ACCESS TO CONTROLLED SUBSTANCES
FOR MEDICAL PURPOSES**



SALUD
SECRETARÍA DE SALUD



ACCESS TO CONTROLLED SUBSTANCES FOR MEDICAL PURPOSES

Cofepris 
Comisión Federal para la Protección
contra Riesgos Sanitarios

December 2017



PANORAMA

The risk to which the abuse of narcotic and psychotropic substances can lead, the need of these for therapeutic and scientific uses, as well as the concern for the growing tendency of production, demand and illicit trafficking, makes necessary the intervention of health authority in regard to control and surveillance in all fields, from production to use.

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PANORAMA

That is why the Federal Commission for the Protection against Sanitary Risks (COFEPRIS), has detected limitations, both real and presumed, on the availability of all these substances with medical and scientific purposes, in particular, of the most important analgesics for pain treatment.

Therefore, its action is to eliminate these limitations, as appropriate, while avoiding the misuse of substances.

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BACKGROUND

The Strategy for the Control of Pain and Palliative Care was conceived as a result of 2 events:

1. The call of the *National Institute of Oncology* to COFEPRIS to warn of a "shortage" of morphine.
2. Studies by the *World Health Organization* and *Human Rights Watch*, conducted in 2013, which showed that the Mexican population had very limited access to controlled medicines and palliative care in general.

BACKGROUND

In response, the Ministry of Health in 2013 created an **inter-institutional group** in order to conduct an assessment and propose solutions.

The group comprised by the General Health Council, pharmaceutical laboratories, distributors, pharmacies, national health institutes, the Supreme Court of Justice, civil associations and the COFEPRIS, among others, works as a "**technical committee**" that identifies means to:

- **Guarantee the supply of morphine**
- **Conduct a situational assessment in Mexico**
- **Coordinate the regulatory aspects** in the integration of palliative care in the National Health System.

ANTECEDENTES

The **General Health Council Agreement** published on December 26, 2014 entrusted COFEPRIS with:

1. Make known the **general rules** for the use of **special prescriptions** for narcotic drugs.

Through the platform for Electronic Prescriptions

2. Establish necessary means to **speed up** and **guarantee** the availability of the above mentioned medicines.

Through the work of the Rapid Action Group

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ELECTRONIC PRESCRIPTIONS



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The **platform of electronic prescriptions**, launched on June 15, 2015 within the framework of the works for the Control of Pain and Palliative Care, allows medical professionals to process their special prescriptions in a more **agile, quick and safe** way and provides **greater control** of medication thanks to the validation of prescriptions in pharmacy.

Pain Control and Palliative Care

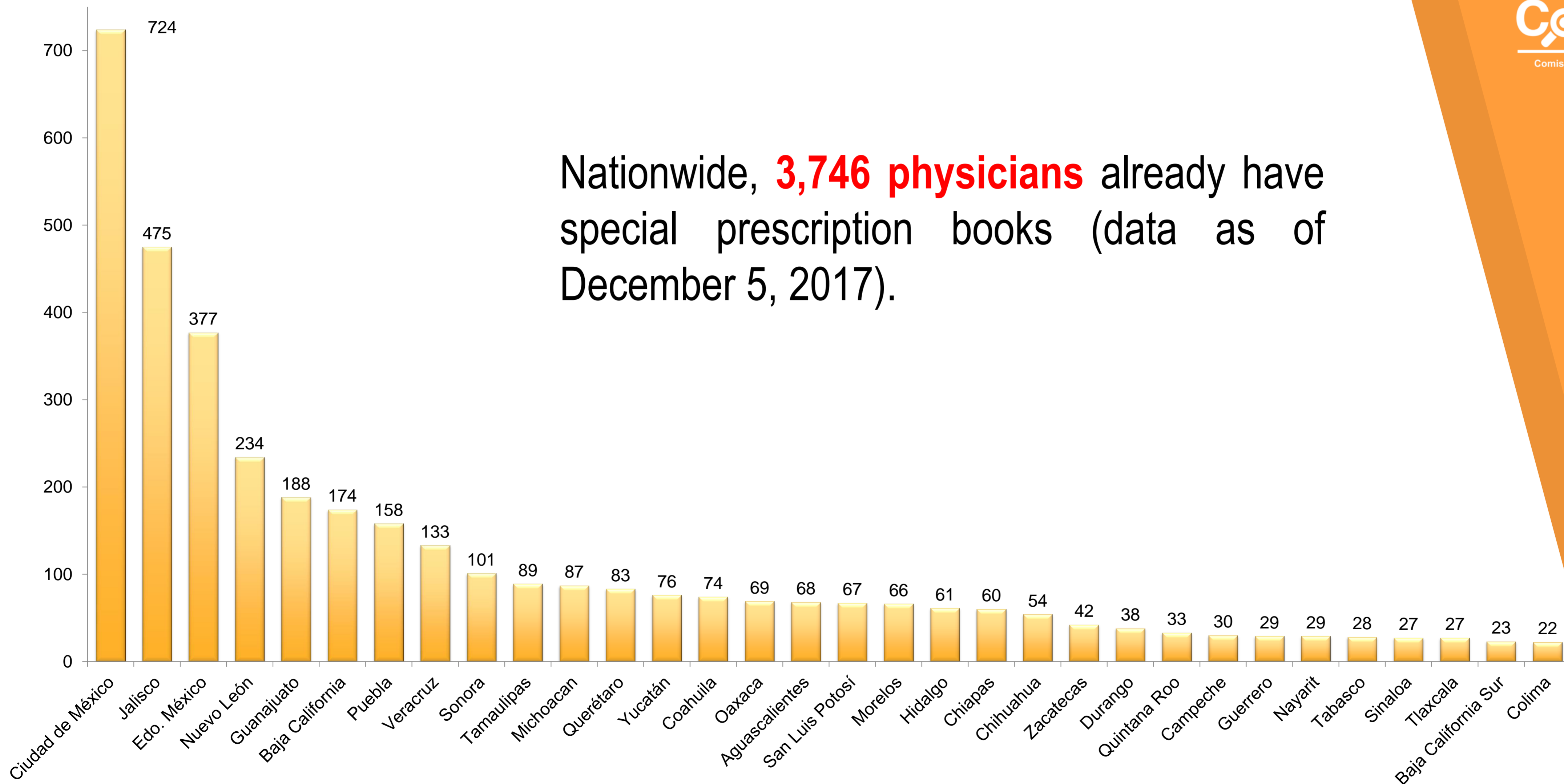
Electronic prescriptions

- ✓ Protection of the doctor's data
- ✓ Processing via web
- ✓ Prescription book with 200 codes per procedure
- ✓ 5-day response achieved
- ✓ Validation of prescriptions in pharmacy
- ✓ Drug traceability

Results*

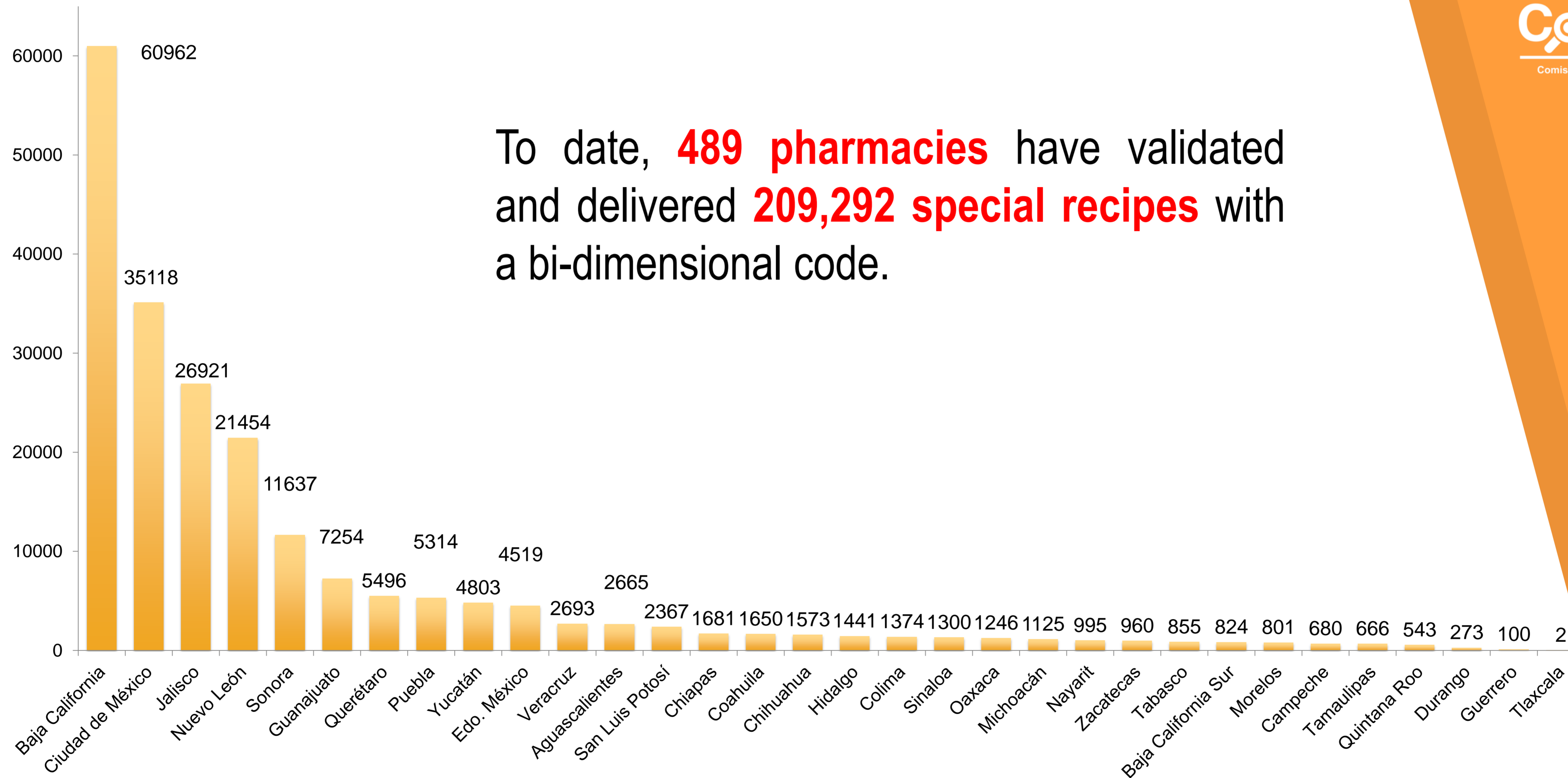
- ✓ **3,746** doctors with special prescription
- ✓ **209,292** prescriptions validated in pharmacies

PHYSICIANS BY FEDERAL ENTITY



Nationwide, **3,746 physicians** already have special prescription books (data as of December 5, 2017).

PRESCRIPTIONS FILLED BY FEDERAL ENTITY



To date, **489 pharmacies** have validated and delivered **209,292 special recipes** with a bi-dimensional code.



CURRENT ACTIONS

CURRENT ACTIONS

1. Continue with the Rapid Action Group for **promotion activities** in the country and the measurement of **stocks** of morphine and other controlled medicines.

2. Perform **statistical analysis** regarding the figures reported in the platform to generate public policies that allow improving its application.

3. Collaborate in the **UNODC** project for the **assessment** of palliative care in Mexico City and generate a scheme that can be replicated throughout the Republic.

4. Work with the General Direction of Health Information to include in the CLUES platform, as well as in the **RadarCISalud** mobile app, information about **private pharmacies** that sell **narcotics**.

5. Promote the implementation of palliative care schemes in the National Health System.

ACURRENT ACTIONS

Guide for Commercialization of Controlled Medicines in Pharmacies



Document that gathers all the regulatory information related to commercialization of controlled drugs in pharmacies.

Content:

- Legal framework
- Self-assessment questionnaire
- Detailed explanation of special prescriptions and validation in the pharmacy portal
- Details on verifications, security measures and sanctions

Guide for Storages and laboratories is a work in progress

CURRENT ACTIONS

HEALTH PROMOTION VISITS

The visits will be carried out in **Mexico City (CDMX)** hospitals and will have two main objectives:

- Support **UNODC** in its task of obtaining a situational assessment on care and availability of controlled substances, to guarantee access to the population.
- Carry out the application of the "**Guide for the Commercialization of Controlled Drugs in Pharmacies**", to inform the establishments about the applicable guidelines and regulations.

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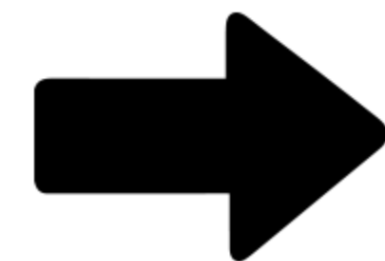
HEALTH PROMOTION VISITS



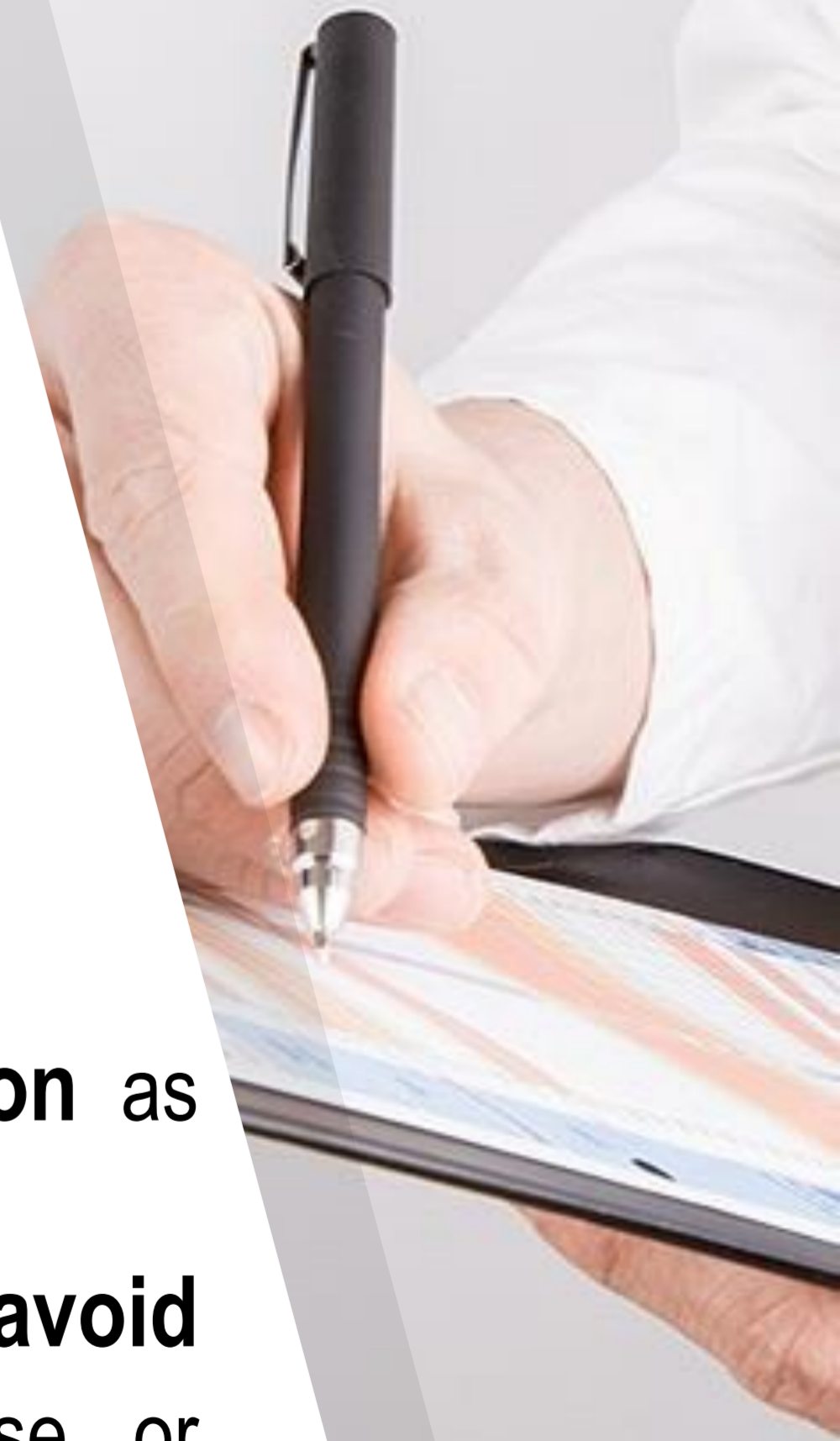
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TRAINING

Provided to the responsible
personnel

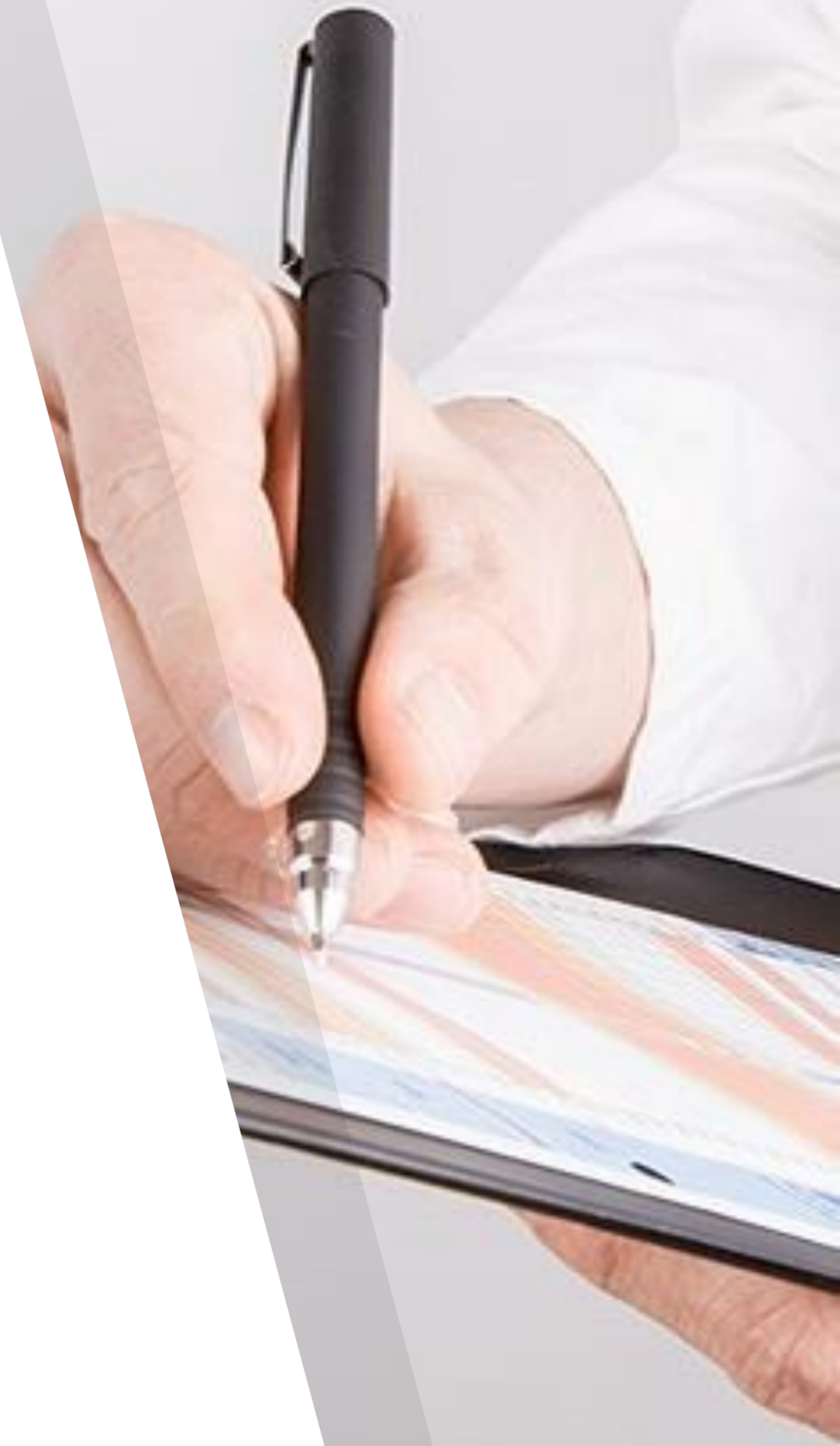


1. Ensure the **traceability** of medicines
2. Identify accurately its **correct dispensation** as well as its legal possession
3. Guarantee supply and, at the same time, **avoid health risks** associated with their abuse or diversion.



CHALLENGES

- Guarantee the availability of substances subject to international control by complying with control measures for the supply of medicines that are required for medical care inside and outside the health institutions, maintaining a balance between the control measures, availability and accessibility.
- Training and awareness of health professionals, policy makers and the general public that reflects in the use of these substances, as well as supply problems, scarcity of resources and inadequate infrastructure.
- Identify the world panorama regarding new narcotics and psychotropic drugs as well as the illnesses for which they are required.



THANK YOU

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**Somos COFEPRIS,
somos ARN**