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FEDERAL COMMISSION FOR THE PROTECTION AGAINST SANITARY  
RISKS  
(COFEPRIS)

EPHEDRINE AND PSEUDO-EPHEDRINE  
CONTROL POLICY IN MEXICO

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# Ministry of Health

FEDERAL COMMISSION FOR THE  
PROTECTION AGAINST SANITARY RISKS  
(COFEPRIS)

CONTROL POLICY OF EPHEDRINE AND  
PSEUDOEPHEDRINE IN MEXICO

Santiago, Chile  
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## CONSIDERATION

The National Development Plan 2007-2012 establishes as one of the main axes of the current administration the combat of narcotraffic as it is one of the most damaging manifestations to the society as a whole, not only because of the high levels of violence it implies, but for the menace it represents to the physical, emotional and moral health of the Mexican people.

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## NORMATIVE AND JURIDICAL FRAMEWORK

- a) General Health Law.
- b) Regulation of Health Products.
- c) Federal Law for the Control of Chemical Precursors, Essential Chemical Substances and Related Equipment.

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## ACTIONS THAT HAVE BEEN IMPLEMENTED

IN ORDER TO AVOID THE DIVERSION OF EPHEDRINE AND PSEUDOEPHEDRINE TO ILEGAL PURPOSES IN MEXICO, THE FOLLOWING MEASURES AND DISPOSITIONS REGARDING PSEUDOEFEDRINE MANAGEMENT AND CONTROL HAVE BEEN ESTABLISHED SINCE 2003 AND REINFORCED FROM 2005:

- From 2003 it is required to those who request sanitary permits before the importation of ephedrine and pseudoephedrine to present its annual previsions of consumption, which may be adjusted by the sanitary authority according to the legitimate needs.

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## ACTIONS THAT HAVE BEEN IMPLEMENTED

- The authority required that for security reasons, transport of these substances is carried out under custody and vehicles are mapped by the GPS system from the point of entry into the country to the importing pharmaceutical laboratory building.
- In 2005, import permits for distributors or brokers of ephedrine and pseudoephedrine as raw material were cancelled. Likewise, it was established that the import permits could be issued up to a maximum of 500 kilograms.

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## ACTIONS THAT HAVE BEEN IMPLEMENTED

- Self regulation agreements were signed with the main chambers of pharmaceutical distributors and wholesalers (ANAFARMEX y DIPROFAR), to establish limits for the sale to the public of medicines containing pseudoephedrine.
- Reclassification of medicines containing ephedrine or pseudoephedrine, from free access medicines to controlled products only sold under a medical prescription. (II Group or Fraction of the article 226 of the General Health Law.

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## ACTIONS THAT HAVE BEEN IMPLEMENTED

- Ephedrine and pseudoephedrine were only permitted to enter the country through three custom points: The International Airport of Mexico City, the Naval Port of Manzanillo, Colima and the Naval Port of Veracruz, Veracruz.
- Since November 2003 it was arranged that the application of the National Drug Control System (NDS), informatical tool provided by the UN Office on Drugs and Crime (UNODC), recognizing Mexico as a pioneer on this tool.

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## ACTIONS THAT HAVE BEEN IMPLEMENTED

- The substitution of pseudoephedrine by fenilephrine was negotiated with the pharmaceutical industry and accepted. In order to guarantee this measure the sanitary registrations have been prioritized and the payment of rights have been exempted.
- The recall from the market and destruction of medicines containing pseudoephedrine.

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## ACTIONS THAT HAVE BEEN IMPLEMENTED

- The sanitary authority has substituted the respective formats, incorporating more security elements such as special paper, ink and key codes, with the objective of preventing the falsification of import permits.
- Review and continuous updating of national and international dispositions in drug control issues.

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## ACTIONS THAT HAVE BEEN IMPLEMENTED

- All the actions mentioned caused a significant decrease in the ephedrine and pseudoephedrine imports in Mexico. As it can be corroborated in the archives of UNODC and only for establish volumes of reference, the imports of pseudoephedrine in 2004 were approximately 230 tons while in 2007 they were 11.8 tons.

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## Agreement

AGREEMENT WHICH ESTABLISHES  
PROTECTION MEASURES REGARDING  
HUMAN HEALTH TO PROHIBIT THE USE  
AND CONSUMPTION OF  
PSEUDOEPHEDRINE AND EPHEDRINE.

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## Considering that ...

- Although the pseudoephedrine and ephedrine are chemical precursors regulated by the Health General Law and the Federal Law for the Control of Chemical Precursors, Essential Chemical Substances and Related Equipment, these substances have been diverted for the illicit production of narcotics.

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## Considering that ...

- The relation between risk-benefit represents a negative balance for the health public, given that the use of the mentioned substances are diverted to produce synthetic drugs which have a high addictive potential and represent a severe menace for the physical and mental health of the exposed population, especially the youth.

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## Considering that ...

- Although the medicines that contain pseudoephedrine or ephedrine are therapeutically useful, they are not indispensables with exception of the ephedrine as an injectable solution;
- Taking into account this information, result imperative to develop the necessary actions to prevent the elaboration of illicit products that represent a risk for the population, such as the methamphetamines or any other illicit drug.

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## Considering that ...

- The sanitary authority, in accordance with the actions of the Mexican government, to combat the production and traffic of synthetic drugs has reinforced the sanitary strategy to control the imports of pseudoephedrine and ephedrine, based on three main directions: strengthening of the law, application of policies against the sanitary risk and a close relationship with the pharmaceutical industry.

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## First

- It is prohibited with the established exceptions in the numerals second and third of the current Agreement, the use of pseudoephedrine and ephedrine in the process of manufacture of medicines or any medical product, either as a raw material, active pharmaceutical ingredient, chemical precursor, essential chemical or any other function.

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## Second

- The Agreement prohibits the production, distribution and commercialization of the medicines containing ephedrine and pseudoephedrine or any medical product that has been elaborated using as one of their components or additives these substances either as raw material or under any other concept, except the ephedrine sulphate in its pharmaceutical form as an injectable solution or for its production.

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## Second

- The use and acquisition of pseudoephedrine and ephedrine will be authorized to the agencies, entities or institutes that require them for the development research or to be in possibility to execute their attributions of surveillance or their activities of toxicological analysis.
- In these cases the authorization will be issued by the Federal Commissioner for the Protection from Sanitary Risks, and the exercise of this attribution could not be delegated to any other official with an inferior hierarchical level.

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## Third

- The Agreement prohibits the imports of medicines or any other health product that has been elaborated using as one of their components or additives, the pseudoephedrine or ephedrine, with the exception before mentioned, as well as the import of these substances as raw material or under any other concept.

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## Fourth

- The laboratories, storages and other establishments that have medicines or raw material inventories of the mentioned substances will have to report them to the Federal Commission for the Protection against Sanitary Risks no longer than 15 working days from the date in which the Agreement takes effect.

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## Fourth

- In the case of the drugstores, when the prohibition takes effect they will have to collect the products with their distributors in order to proceed to their destruction, except the ephedrine sulphate as injectable solution.

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## Fifth

- The distributors and the owners of the sanitary registrations of the medicines that contain pseudoephedrine or ephedrine, except the ephedrine sulphate as injectable solution, will have to pick up and destroy the medicines. They will have to notify about the destruction of these substances with 15 working days in advance, indicating the place and hour in which the destruction will be carried out in presence of the Federal Commission for the Protection from Sanitary Risks. It is also required an inventory of the medicines or raw materials that will be destroyed.

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## Sixth

- Any process of import either raw material or finished product will have to be suspended. The Federal Commission for the Protection against Sanitary Risk has the attribution to cancel all the import permits that are in process, with exception of ephedrine sulphate in its pharmaceutical presentation of injectable solution or for the manufacture of this one.

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## Sixth

- If some lot of pseudoephedrine, ephedrine or medical product that contains them is introduced to the country, it will be destroyed under the terms of this Agreement and the person in charge of the lot should notify to the Federal Commission for the Protection from Sanitary Risks.

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## Seventh

- When the present Agreement takes effect, the Federal Commission for the Protection from Sanitary Risks will have to count with the necessary conditions to receive the destruction requests and if it is the case, to coordinate the transportation of the medicines and substances for their destruction.

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## Eighth

- The surveillance of the fulfillment of this Agreement corresponds to the Federal Commission for the Protection against Sanitary Risks. The content of the Agreement will have to be observed in the sanitary practices of evaluation, inspection and surveillance as well as in the use of safety measures and sanctions.

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Thank you very much  
for your attention !!

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