

THE INSPECTION OF SUBSTANCES SUBJECT TO SPECIAL CONTROL THE CASE OF CONTAMINATED FENTANYL IN ARGENTINA

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GLOSSARY

MSAL Ministry of Health of the Nation

ANMAT National Administration of Drugs, Food and Medical Technology

INAME National Institute of Medicines

DSSCE: Department of Substances Subject to Special Control

DFYC#INAME: INAME Directorate of Inspection and Control

JDI#INAME: Head of the INAME Inspection Department

1. INTRODUCTION

The objective of this research work is to analyze the causes that led to the death of 174 people so far, hospitalized in our country after receiving treatment with FENTANYL HLB / FENTANYL CITRATE, concentration 0.05 mg/ml, in the pharmaceutical form injectable solution, 5 ml vial (presentation x 100 ampoules, according to VMN); lot 31202, expiration 09/26; Certificate no. 53.100 Pharma, whose ownership corresponds to the firm **HLB PHARMA GROUP SA**, prepared by **LABORATORIOS RAMALLO SA** and its impact.

The ultimate purpose of this report is to evaluate the regulations and anticipate situations that could occur, assess the impact, the effects and their relationship with the health system and with the substantive processes carried out by the control body, and make the appropriate decisions to avoid or reduce their negative effects on public safety and health, the security of the health system, the administration, the national economy, and whether public health and the oversight and control system of our country are at risk.

Fentanyl is a potent synthetic opioid drug approved by ANMAT for use as an analgesic (pain reliever) and anesthetic. It is approximately 100 times more potent than morphine and 50 times more potent than heroin as a pain reliever. It is also sold and used illegally.

It is defined as a substance subject to special control, and therefore its import, export, manufacture, marketing, distribution, and use are governed by a special regulatory and international monitoring regime, through the INCB, and a national regime called the "Federal Voucher." As a medicinal product, it is subject to compliance with: the drug traceability and market recall system, good manufacturing and control practices, and all their provisions.

The analysis process was based on research and study of the current legal framework applicable to the control of medicines and substances subject to special control, as well as an analysis of the procedures and their impact on the various actors involved in the system for monitoring and controlling substances subject to special control under the jurisdiction of ANMAT and INAME. It also relied on the search and compilation of open sources, audit reports from the government oversight bodies AGN and SIGEN, the ANMAT website, the Public Prosecutor's Office report in the "Fentanyl" case, the Official Gazette, and articles and news reports from various media outlets related to the topic.

POLICE POWER:

It is the set of coercive measures established by law to ensure that individuals adjust their activities to a purpose of public utility.

Police power restricts individual rights, not only to safeguard public safety, morality, and health, but also to

promote the general welfare, the common good.

In the language of administrative law, the term "police" refers to the limitation, by an authority for reasons of general or public interest, of an activity of citizens, without that activity ceasing to exist as a private activity; it is merely regulated. It remains free insofar as it is not expressly restricted by police regulations.

SANITARY POLICE POWERS: The purpose of the sanitary police is to ensure public health. Their area of jurisdiction can be national or local.

INSPECTOR: From the Latin inspector, -ōris (used to form abstract nouns)

1. adj . That recognizes and examines something. U. tcs

2. m. and f. Public or private employee in charge of the inspection and oversight of the sector to which they belong and from which their position derives its special title. Police inspector, postal inspector, customs inspector, education inspector, railway inspector.

Inspector General

1 m. and f. official who, due to his high rank, is responsible for overseeing the entirety of a state service and the personnel who carry it out.

The health inspector is a public employee responsible for inspection, oversight, and exercising the functions of a health police officer. The purpose of this police force is to safeguard public health and ensure compliance with current legal regulations. Its area of jurisdiction can be national or local. In the case of ANMAT inspectors, they are appointed by the agency's highest authority and the vast majority are professionals hired under Article 9 of the National Public Employment Law (placing them in a disadvantaged and vulnerable position within the hierarchical structure due to their precarious employment status and lack of opportunities for permanent state positions, as ANMAT has not held competitive examinations since 1996).

CONTROL: This is the review and verification of the composition, quality, effectiveness and safety of products regulated by ANMAT.

INSPECTION: This involves monitoring compliance with regulations. It entails inspecting, investigating, intervening, and inquiring about establishments dedicated to the production, import, packaging, and/or sale of goods, as well as their raw materials and finished products.

To monitor is to inspect, investigate, control, investigate, and probe. Inspection constitutes the "eyes and ears" of surveillance systems. It is a crucial step in understanding and accurately assessing a product's status throughout the production and distribution chain, from raw material production to final product consumption. Clearly, these "eyes and ears" cannot be present everywhere their intervention is needed. The police operate as a control or monitoring tool, exercising their "health police power." From a constitutional perspective, the national and provincial governments have the authority to regulate and limit, legislatively and/or administratively, the exercise of rights. In this sense, there is talk of concurrent powers between the sovereign State and the autonomous member states (Arts. 1, 5, 75, 121, 122, 125, 126, CN) (PTN, Opinions, 116:446). The Constitution expressly preserves for provincial and municipal authorities the police power over establishments of national interest and federalized jurisdictions (Art. 75, item 30).

The Supreme Court of the Nation, in repeated pronouncements, has validated this interpretation, in the sense that the police power is in charge of local governments, but in a shared or concurrent manner with the National State (arts. 75 and 125, CN).

These concurrent powers enable both the national and provincial governments to regulate the exercise of rights, provided that no incompatibility arises, as these powers are mutually exclusive, belonging to one or the other government, and are delegated or reserved within the constitutional framework. Thus, ANMAT has jurisdiction over the inspection, control, and oversight of, among other things, medications and substances subject to special control.

RISK-BASED INSPECTION: Inspection carried out by official control services at laboratories and pharmaceutical establishments to verify compliance with all legal requirements established in current legislation, with a focus especially directed towards the main risk factors associated with medicines and Good Practices.

Risk-based inspection establishes the premise that if all necessary control measures are implemented for the risk factors associated with a product and/or process, safety risks are minimized. Risk management in industry is carried out according to risk management principles and is essentially equivalent to a "zero defects" system. In the event of finding a defective product, risk-based inspection must determine where the system failed or

failed, or what hazard was not properly controlled. There are three types of responsibilities with different nuances: monitoring compliance with hygiene standards to prevent health risks, addressing potential fraud that harms consumers, and advising companies to promote improvements in hygiene and sanitation standards.

SURVEILLANCE: Surveillance and Surveillance Systems function as a set of methods, observations and disciplines that allow, during the marketing stage of products, the detection of adverse reactions and unforeseen undesirable effects.

HEALTH SURVEILLANCE: It is the set of actions aimed at preventing, reducing or eliminating health risks, through the application of a comprehensive, cross-cutting and panoramic system

PHARMACOVIGILANCE: Monitoring applied to drugs, whether for adverse effects or quality deviations.

ADVERSE EVENT: In the context of pharmacovigilance and outside of a clinical trial: Any inappropriate medical occurrence in a patient or clinical trial subject who has been administered a medicinal product and that does not necessarily have a causal relationship with this treatment. Therefore, an event may be any unfavorable and unintentional sign (e.g., an abnormal laboratory result), symptom, or illness temporarily associated with the use of a medicinal product, whether or not it is considered related to that medicinal product.

TRACEABILITY: Enables the rapid detection of medications or products throughout the supply chain. It guarantees product quality and safety for the benefit of patients. It provides real-time control of the number of transactions and operations of laboratories, logistics operators, distributors, drugstores, pharmacies, etc. All those involved in the manufacturing, distribution, marketing, and sales chain are legally obligated to comply with traceability data requirements. This data must be available upon request by health authorities, and they must have a standardized operating procedure for traceability and conduct at least one annual exercise to determine recovery times and percentages in the event of a deviation. Forward traceability allows for the location of product sales units (e.g., 1 box of 20 tablets of 100 mg) throughout the supply chain, all the way to the point of sale. Backward traceability allows for the

tracking, identification, and origin of the raw materials used to manufacture a batch . product code (coding system that uses the year of manufacture and a sequential number issued by the packaging company itself), identify the production line, the operators who participated, the quality parameters measured, deviations detected, compliance with quarantine before release, etc.

NATIONAL TRACEABILITY SYSTEM: Traceability by product unit and use. A tracking and tracing system placed on the packaging (retail unit) of medicinal products, allowing the distribution chain of each finished product unit to be reconstructed individually. Unique and individual identification of each unit of medicinal products to be marketed.

As detailed on the ANMAT website, it "Ensures efficient financing for specialized, highly complex, and/or catastrophic treatments." It applies to the ANMAT-PAMI Agreement of 2016 and the ANMAT-National Cancer Institute Agreement.

The monitoring of "narcotics and psychotropic substances, such as fentanyl , morphine, oxycodone , methadone, flunitrazepam , cannabidiol , ketamine and propofol , is carried out only at the jurisdictional level by the Paper Voucher System that must be made available to the National Government upon the express request of ANMAT.

ANMAT Provision 10564/2016, signed by the then Administrator Carlos Chiale , removes fentanyl from the traceable substances.

GMP: Good Manufacturing Practices and Control

CRITICAL DEFICIENCIES: These are activities or processes that can result in immediate and concrete harm to the consumer's health, in some cases death or irreversible damage. This applies to any deficiency that can directly affect product quality, and includes findings such as fraud and falsification of data or products.

MAJOR DEFICIENCIES: These are activities or processes not classified as critical that may result in a product that does not comply with its marketing authorization or that indicate a failure in the batch release procedures.

Some major deficiencies may be considered critical in certain contexts, and in the list of deficiencies they are identified with the sign (↑)

A set of major deficiencies can lead to a critical deficiency if it involves serious failures in the quality or

manufacturing system.

CRITICAL DEVIATION: This applies to any deficiency that could directly affect the quality, safety, and efficacy of the product, and includes findings such as fraud and falsification of data or products. These are activities or processes that can result in immediate and concrete harm to consumer health.

MAJOR DEVIATION: These are activities or processes not classified as critical that could result in a product that does not meet its marketing authorization or that indicate a failure in batch release procedures. Some major deficiencies may be considered critical in certain contexts, and are identified in the deficiency list with the symbol (↑). A set of major deficiencies can lead to a critical deficiency if it involves serious failures in the quality or manufacturing system.

NC: Non-conformity

OOC: Out-of-specification remarks

ADMINISTRATIVE SANCTIONING ACTS (CERTIFICATE OF NO PENALTIES): This certification is requested by companies and/or laboratories regulated by ANMAT (National Administration of Drugs, Food and Medical Technology) that participate in public tenders, since, if they have registered sanctions for non-compliance with health regulations, they would be legally ineligible to participate. The Administration verifies that the laboratory is duly authorized and has no record of sanctions for violating current regulations. Clarifications: When completing the Application Form for Certificates of No Penalties, the fields "Tender Number" and "Opening Date" must be filled in for all Operation Types except "Supplier Registration" and "Other."

INSPECTION WITH FAVORABLE CLASSIFICATION. COMPLIANCE WITH THE CURRENT LEGAL AND HEALTH REGULATIONS: Indicates the level of sustained compliance, based on post-inspection classifications by ANMAT, for the maturity of quality systems and compliance with current legal regulations to avoid risks to health, address potential fraud that threatens the consumer, and ensure public safety and health.

PERCENTAGE OF LABORATORIES INSPECTED BASED ON RISK: Prioritizes inspections of laboratories classified as

critically risky, to optimize efficiency and resources

ANALYTICAL METHOD VALIDATION COVERAGE (CALIBRATED): Verifies compliance with IQ/OQ/PQ in facilities and equipment, being essential for ensuring the quality, safety and effectiveness of GMP processes, and offering credibility of results.

NUMBER OF OUT-OF-SPECIFICATION PRODUCT RESULTS PER BATCH ANALYZED IN THE LABORATORIES: Allows measuring the robustness of analytical controls during inspections, key in batch release metrics by ANMAT.

MEDICINE: Any preparation or pharmaceutical product used for the prevention, diagnosis or treatment of a disease or pathological condition, or to modify physiological systems for the benefit of the person to whom it is administered.

IFA: Active pharmaceutical ingredient

LOT: Quantity of a product obtained in a production cycle through continuous stages and characterized by its homogeneity, for which a written record is kept.

PSYCHOTROPIC: Any natural or synthetic substance capable of influencing bodily functions/psychic effects due to their action on the Central Nervous System (CNS).

PSYCHOTROPIC DRUG: Any pharmaceutical product composed of psychotropic substances, used as the object of the treatment of mental or neurological conditions.

NARCOTICS: Any psychotropic substance, with a high potential to produce abusive behavior and/or dependence (psychic/physical, with a profile similar to morphine, cocaine, marijuana, etc.), that acts by itself or through conversion into an active substance that exerts said effects.

CONTROLLED SUBSTANCES: Psychoactive substances and their precursors whose distribution is prohibited by law or restricted to medical and pharmaceutical uses. The substances currently subject to this control vary from country to country. The term is often used to refer to the psychoactive substances and their precursors mentioned in Chapter V of the 122 international drug conventions (Single Convention on Narcotic Drugs of 1961, as

amended by the 1972 Protocol; 1971 Convention on Psychotropic Substances; 1988 Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances). At both the national (such as the 1970 U.S. Controlled Substances Act) and international levels, controlled substances are usually classified into categories that reflect the different degrees of restriction on their availability.

CHEMICAL PRECURSORS: These are chemical substances of mass, industrial and commercial use that are susceptible to being diverted from their legal use to be used in the processing and/or production of different types of illicit natural or synthetic drugs.

FENTANYL: A potent synthetic opioid drug approved by ANMAT (Argentina's National Administration of Drugs, Food and Medical Technology) for use as an analgesic (pain reliever) and anesthetic. It is approximately 100 times more potent than morphine and 50 times more potent than heroin as an analgesic. It is a medicinal substance covered by Laws No. 23,737 (narcotics and psychotropic substances since 1991) and No. 17,818 (legal narcotics, updated by Resolution No. 2,622/88). The lists of narcotics have been updated, and Law No. 23,737 includes at least 133 analogues of this drug. Fentanyl was reinstated on the lists following the recent health crisis. It is also illegally traded and used.

LABORATORY: Any individual or legal entity authorized by ANMAT (National Administration of Drugs, Food and Medical Technology) to manufacture, process, package, import, and/or export Active Pharmaceutical Ingredients (APIs). In this case study, HLB PHARMA and Ramallo Laboratories. As established by the regulations governing this matter, the owner and the technical director of the establishment are jointly and severally liable for the release of drug batches, in accordance with the quality standards required by current legislation. Laboratories holding registrations for medicinal products that use or contain chemical precursors in their products must inform the National Administration, 45 days in advance, of the date and time when the weighing and mixing of the aforementioned substances will take place.

PHARMACY: An establishment dedicated to the distribution of medications, both on its own account and wholesale, in accordance with Law No. 17,565 and its implementing regulations, or their equivalent in

jurisdictional regulations. Pharmacies that exclusively distribute high-cost medications are called specialized pharmacies; while comprehensive pharmacies focus on over-the-counter and prescription medications for outpatient use and offer a high level of service and frequent delivery logistics. They are legally required to maintain a traceability system for the products they sell.

IMPORTER: A natural person who imports products and is registered with the Customs Importers Registry, ANMAT (National Administration of Drugs, Food and Medical Technology), and, in the case of SSCE (Specialized Drug Surveillance System), SEDRONAR (National Secretariat for Drug Prevention and Control). The importation of medications classified as psychotropic or narcotic drugs must comply with current national and international legal regulations, such as those of the INCB (International Narcotics Control Board), a system that ensures stock control and traceability between member states.

2. REPORT

2.b. Conflict

“A conflict arises when incompatible interests appear between actors” (R. Entelman)

This is a variable-sum conflict. Type: permitted versus prohibited

Static analysis of main and third-party actors.

Identification of Actors in the conflict: common characteristic “Collective Actors”, some organized, such as the HLB Pharma Laboratory The following groups are involved : the Ramallo laboratory; pharmaceutical chambers; ANMAT (National Administration of Drugs, Food and Medical Technology); the National Ministry of Health; victims and their families who have not yet organized themselves; hospitals; and, among others, the provincial and municipal health authorities; the Fentanyl Investigation Commission of the Chamber of Deputies; professional associations; the National Union of Civil Servants (particularly the Health Delegation); and the Ministry of Security. We will only analyze the structure and operation of ANMAT and briefly examine the main individual actors from the HLB and Ramallo laboratories and ANMAT. We will not address the other actors.

The pharmaceutical sector defines the production profile of each laboratory and determines its affiliation with the various Chambers:

Argentine Chamber of Pharmaceutical Laboratories (

CILFA) formed in 1964 As its name indicates, it brings together companies of national origin.

The Argentine Chamber of Medicinal Specialties (CAEME), established in 1925, brings together laboratories or pharmaceutical and biopharmaceutical companies with foreign capital.

The Chamber of Pharmaceutical Laboratories (created in 1959) represents pharmaceutical laboratories specializing in medicinal products, primarily those with Argentine capital. Its objective is to coordinate the actions of its members, collaborate in management, and provide advice.

Argentine Chamber of Generic and Hospital Use Drug Producers (represents national laboratories specializing in the production of generics and sales to state entities)

The Argentine Chamber of Over-the-Counter Medicines (CAPEMVEL), comprised of both national and international laboratories that produce over-the-counter medicines, is part of WSMI World. Self Medication Industry NGO related to the WHO

Both laboratories, HLB PHARMA GROUP and Ramallo, are national companies, which were formed in the last twenty years.

ANMAT is characterized as a collective, public actor with a hierarchical and subordinate relationship within the National Public Administration (APN). It has expanded and consolidated its structure and that of its institutes, as well as its management and decision-making processes, over at least the last fifteen years. During this time, its operational structure has shifted from having mostly permanent staff to having, as of today, almost 80% of its personnel hired under the provisions of Article 9 of the Framework Law on Public Employment.

It is worth mentioning that ANMAT staff, regardless of their employment status, are covered by two sectoral collective bargaining agreements of the National Public Administration (APN): the National System of Public Employment (SINEP), which applies across the entire public administration and includes professional, technical, and administrative profiles (the latter being by far the most numerous compared to the number of existing technicians and professionals); and the sectoral agreement for Professional Staff of Hospital and Healthcare Establishments and Research and Production Institutes under the Ministry of Health of the Nation (Decree 1133/2009). According to the lists published on the agency's website, approximately 65% of staff are classified under SINEP and 35% as Health Professionals.

Born after the occurrence of two tragic events:

- August 11, 1992

In Argentina, news spread of a strange illness of unknown origin developing in the city of La Plata. Victims arrived at hospitals with acute poisoning, including nausea, vomiting, and dizziness; all reported having consumed Huilen syrup. By September, the death toll had risen to 21. It was later discovered that the cause of the illness was poisoning from a propolis -based tonic produced by "Laboratorios Huilen," which contained diethylene glycol, an alcohol unfit for human consumption. The incident triggered a major public health crisis in the country.

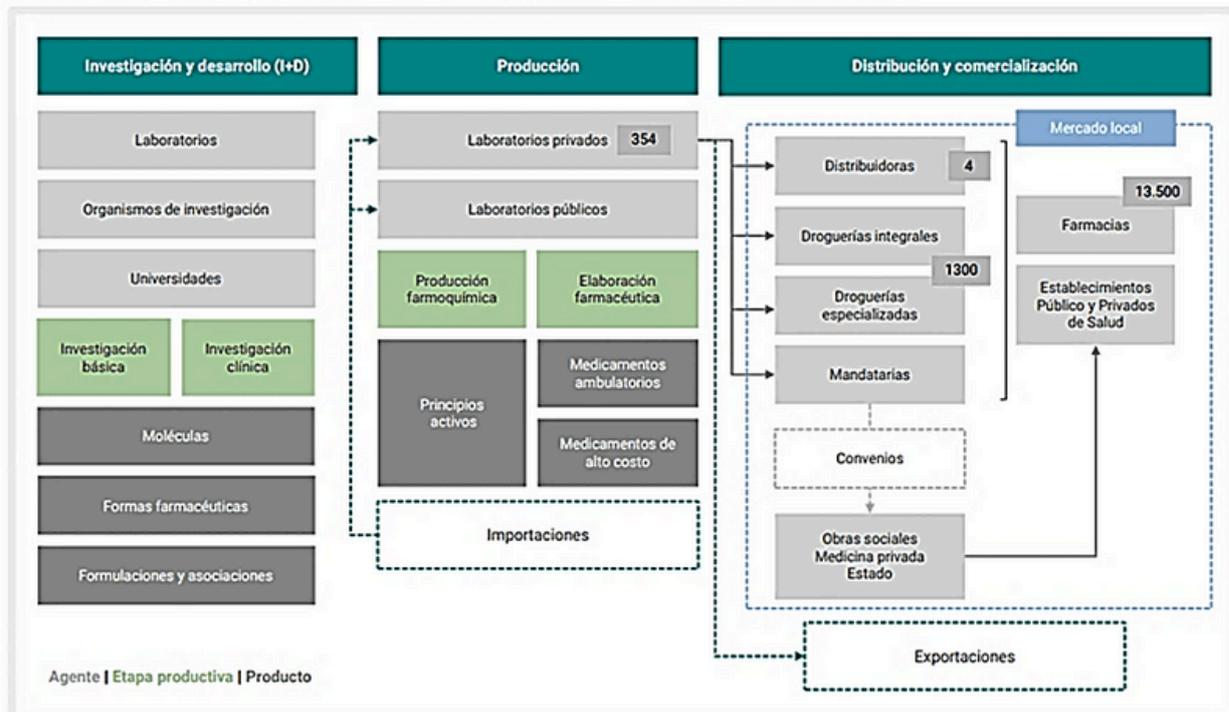
- February 21, 1993

Mansero " and "Soy Cuyano" wines were adulterated killed more people than propolis. Twenty-seven people died, and the scandal spread beyond Argentina's borders: there were cases of poisoning in Montevideo, and even Poland investigated the alleged distribution of a batch.

Thus, on August 20, 1992, ANMAT was established by decree 1490/1992 under the Ministry of Health. A decentralized agency of the National Public Administration, it is technically and scientifically dependent on the regulations and directives issued by the Secretariat of Policies, Regulation and Institutes, with economic and financial autonomy and jurisdiction throughout the national territory. It was created in response to the need for a national agency that would encompass the functions of registration, control, oversight, and monitoring for the protection of human health and safety, ensuring the safety and quality of products, processes, technologies, and materials consumed or used in medicine, food, domestic use, and human cosmetics, and overseeing the activities and processes involved in or related to these areas.

It began operating organically in late 1993, when Decree 2098 established its first and second-level organizational structure, which was later modified by, among other regulations, Decree 1271/2013 and ANMAT Provision No. 4548/2014. Its structure was consolidated through ANMAT Resolution No. 761/2019, which establishes the first and second-level operational organizational structures currently in effect. The ANMAT first-level structure and the INAME second-level structures relevant to this study are attached. A simple glance at its organizational structure reveals the fragmentation of INAME's controls and inspection areas into different operational units: simple directorates, departments, and services, according to the subject matter to be inspected

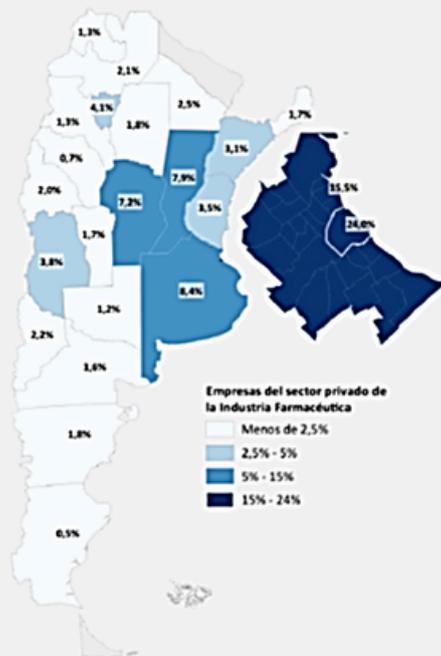
FIGURA 3. CADENA DE VALOR DE LA INDUSTRIA FARMACÉUTICA



Fuente: reproducido de Ministerio de Economía (2022).

Subsecretaría de Programación Microeconómica
Configuración territorial

La producción de la cadena está concentrada en Ciudad de Buenos Aires y GBA provincias



- La producción farmacéutica se concentra en los grandes centros urbanos. En el año 2016 se estimaron alrededor de 449 empresas activas del sector privado en la industria farmacéutica (OEDE, 2018). Cerca del 40% de los locales* de empresas del sector (incluyendo sucursales) están ubicados en la Ciudad Autónoma de Buenos Aires (CABA) y en el Gran Buenos Aires (GBA), siguiendo en importancia, con una participación menor, resto de Buenos Aires (9,0%), Santa Fe (7,9%) y Córdoba (7,2%).
- La distribución territorial es explicada por la concentración de la población en estas urbes que determinan los principales focos de consumo, a la vez que también es donde prevalecen los organismos gubernamentales que licitan y adjudican compras de los productos farmacéuticos para ser utilizados en los programas de salud pública (MinCyT, 2010).

* Las empresas declaran sus ocupados según sus locales en cada provincia (plantas productivas, locales auxiliares o establecimientos comerciales). Por lo tanto, la suma de dichos locales supera al total de empresas que operan efectivamente en el sector. Total de locales: 1.032.

Fuente: SSPMicro con base en OEDE.

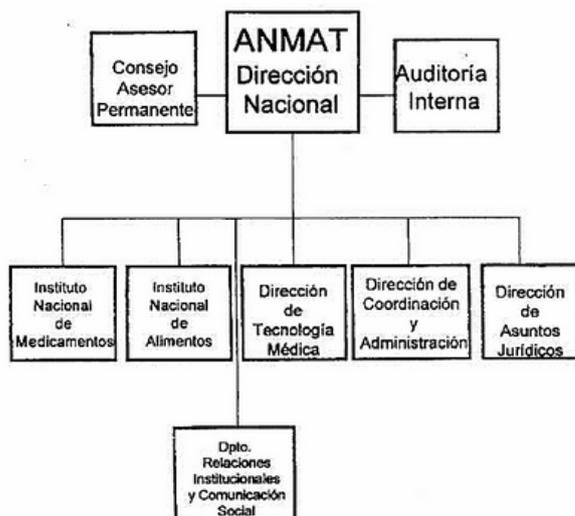
(i.e., inspection of: GMP, first batch, pharmacovigilance , market surveillance, licensing, foreign trade, SSCE, National Reference Laboratory (which handles microbiology inspections, for example).

In some cases, these operational units do not even share a common directorate, and in others, such as the Department of Control of Substances Subject to Special Control and its service, they report directly to the INAME National Directorate.

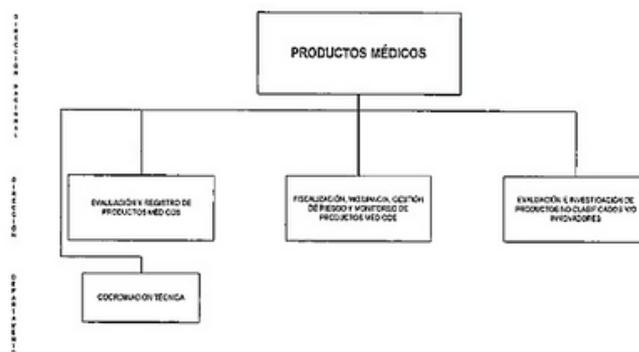
In this state, a brief review of the personnel in the department as a whole deserves special attention, taking into account the national public employment system that applies to it; which will be Permanent Staff, Staff Contracted by Article 9°, Staff with temporary designation in the permanent staff (those who have the function of heads, coordinators and directors) and extra-career staff .

ANMAT employees fall under the public employment regime, covered by the General Collective Bargaining Agreement approved by Decree No. 214/06, and specifically by the Sectoral Collective Bargaining Agreement (CCS) of the National System of Public Employment (SINEP) and the CCS for Professional Staff of Hospital and Healthcare Establishments and Research and Production Institutes under the Ministry of Health, Decree 1133/09. Like all public servants, they are subject to the general provisions of the law, including, among other matters, disciplinary responsibility as a cardinal principle of the Republic and an inherent power of the administrative function. Responsibility is defined as "the capacity of every legal subject to recognize and accept the consequences of an act freely performed ." Furthermore, they are subject to a Special Incompatibility Regime for all personnel, as set forth in Article 13 of Decree 1490/92 creating ANMAT: - " *It is hereby established that the personnel of the NATIONAL ADMINISTRATION OF DRUGS, FOOD AND MEDICAL TECHNOLOGY (ANMAT) shall be subject to a special incompatibility regime, which establishes that it applies to those who are in the circumstance of:*

- a) maintain a relationship of dependency, permanent or temporary;
- b) to provide professional or other services directly or indirectly; and
- c) being owner, shareholder, partner or director of companies or corporations; provided that such activity or character is presented with companies, corporations or establishments that act in the supply, production, processing, fractionation, import and/or export, storage



ANMAT ORGANIZATION CHART 1



ANMAT 2

and marketing of the products, substances, elements and materials consumed or used in human medicine, food and cosmetics.”

It's worth pausing to mention that some INAL agents, for example, have openly and publicly admitted on social media to working for Pharmanex laboratories for over a year , with the knowledge of higher authorities. <https://youtu.be/VnCbSaXtMc4?si=Vl8CdbPAmvMN1syQ>

Similar situations were found in audits that uncovered links to pharmacies and distributors of medical products, to name a few.

Furthermore, professional staff who hold a degree or higher are classified according to their disciplines in one or another sectoral agreement, and must meet the minimum requirements and conditions established for each of the levels and profiles defined for each position in which the agent is employed.

Thus, graduates in Chemistry, Biochemistry, Biotechnology, Food Science, Medicine, Pharmacy,

Dentistry, Speech Therapy and Nutrition, among others, belong to the Inspection and Control Group of the Decree No. 1133/06 scale, and Accountants, Lawyers, Graduates in Data, in Statistics, belong to the Professional Group of SINEP.

Technical staff, for example, Chemical Technicians, in Clinical Trials, in Food Control, in Food Technology, are classified in the General Grouping of SINEP, as are administrative staff with a secondary degree of Bachelor or Commercial, since there is no technical grouping in this organization, as there is, for example, in CONICET (scientific technical grouping).

According to the personnel lists found online, the most recent publication being July 2025, the list corresponding to 2021 published on the website was randomly selected and an analysis was performed regarding the hiring method and collective bargaining agreement framework. The analysis yielded the following results, which are detailed in the accompanying graphs: Graph of personnel income evolution; Graph of personnel income evolution under Decree 1133/09; Graph of SINEP income evolution; Graph of personnel distribution by grouping and hiring method; Graph by hiring method; and Graph by collective bargaining agreement/grouping. Where it says "SINEP 48" it should be interpreted as SINEP due to a typographical error.

The graphs show that almost 77% of ANMAT agents are contracted and almost 17% are permanent staff; demonstrating that the exception established in the Framework Law for the Regulation of Public Employment for contracting has become the rule and the exception is the permanent staff.

Furthermore, the number of professionals classified under Decree No. 1133/09 is approximately 40%, compared to 60% under SINEP. In the latter, the majority of professionals are classified under the general category, while the majority are classified under the professional and technical categories.

It should be noted that there has been no competitive process for permanent positions since 1996, with the exception of the regularization process implemented during the previous administration, which applied only to a discretionary portion of the workforce.

I will now quote a reflection addressed to the Public Administration and its senior officials: *"WE MUST KILL THE BUREAUCRATIC MEANING. If we don't kill the bureaucratic meaning of 'process it,' the 'process it' mentality will kill us all. That's the reality. That's why we need 750,000 public employees, when we could resolve*

matters with perhaps 250,000 or 300,000. Because, of course, when the boss receives it, it goes to the second-in-command, then to the assistant, and then to the clerk; the clerk alone would be enough to complete the process. Why do I have all those people in front of me? The problem is that we need fewer officials and employees, but we need to pay them better and have them work more, because it's logical: higher pay corresponds to greater effort." We must have the fewest possible employees and pay them as much as possible, and demand that they perform well in their work, not only in the physical work, but also by taking on the responsibility that he, as a civil servant or public employee, is obliged to bear."

List of senior ANMAT authorities by period

2024 to present - Administrator Nélica Agustina Bisio (formerly in Drug Evaluation and Registration, Clinical Trials Department (has two known administrative investigations against her, one initiated by Minister Lugones after the case became public and the other from September 2024 initiated by the then Minister of Health Dr. Mario Russo for her participation in the Pfizer vaccine clinical trials carried out at the Military Hospital. In addition to a criminal complaint processed in the National Federal Criminal and Correctional Court No. 3 of the city of Buenos Aires, headed by Dr. Daniel Eduardo Rafecas) and Sub-administrator, Enriqueta Pearson (former Director of Legal Affairs).

2020-2024 Manuel Limeres - Valeria Garay (previously held positions at ANMAT)

2015-2019 Carlos Chiale – Rodolfo Ledo

2014-2015 Rogelio López – Federico Kaski

2010-2014 Carlos Chiale

2008-2010 Intervention Dr. Ricardo Martínez – Daniel Gollán

2002-2008 Auditor Manuel Limeres

List of INAME authorities by period

August 2025 to present Gastón Morán (during the last fifteen years held other positions in ANMAT-ANLAP-ANMAT -biologicals until August-)

2022-2023 Gabriela Mantecón Fumado (formerly at COMEX INAME)

2022-2022 Matías Gómez (did not last a year - before and now in other positions at INAME)

2020-2022 Marcelo Carignani

2018-2022 Jaime Lazovski

February 2015-December 2015 Raquel Méndez (former

CHART OF PERSONNEL INCOME EVOLUTION

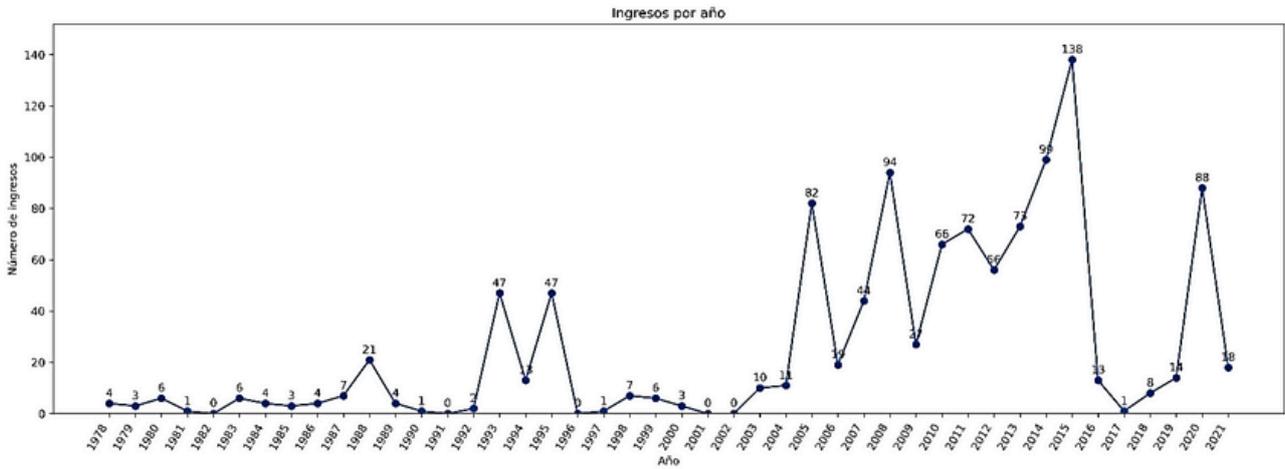


CHART OF PERSONNEL INCOME EVOLUTION DECREE 1133/09

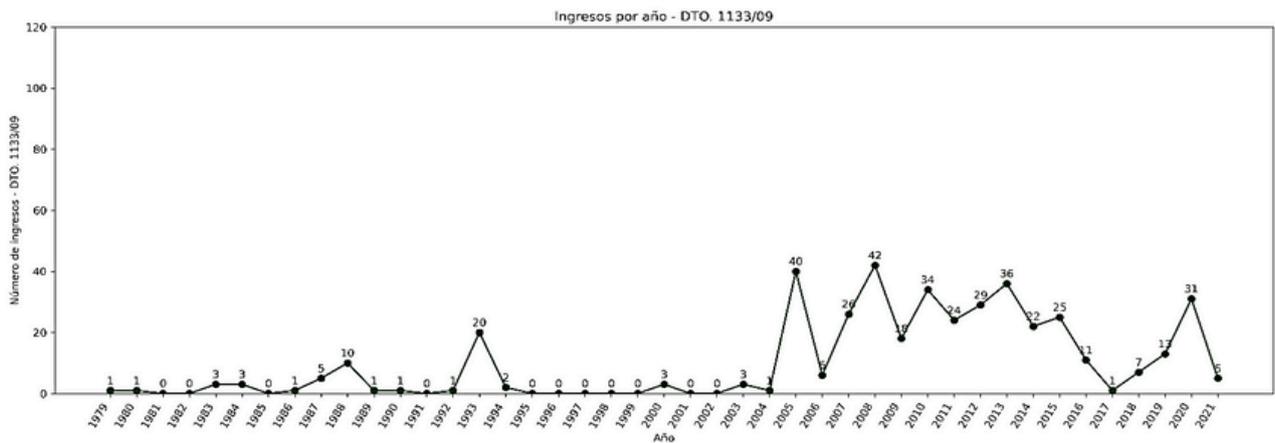


CHART OF SINEP REVENUE EVOLUTION

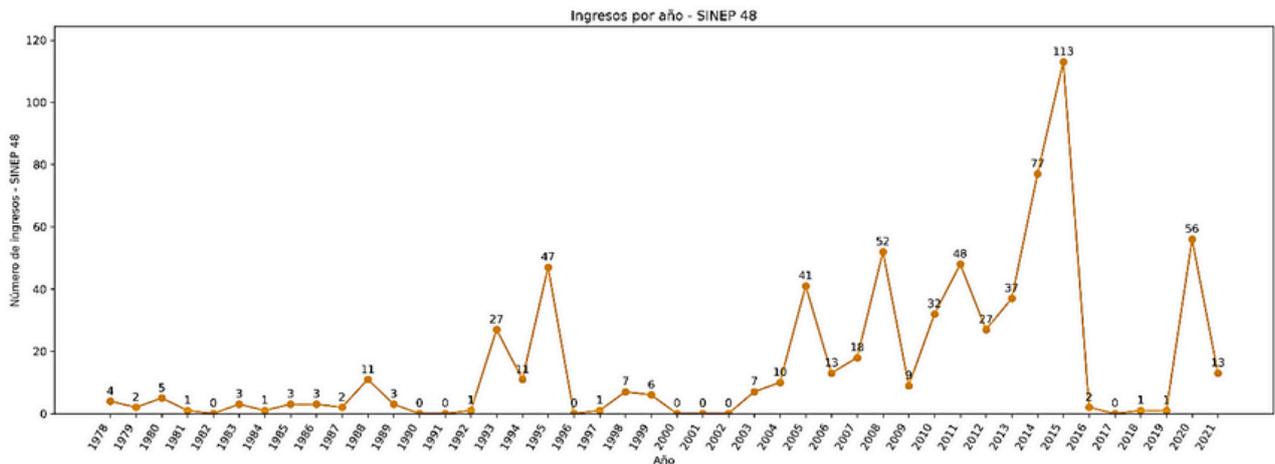
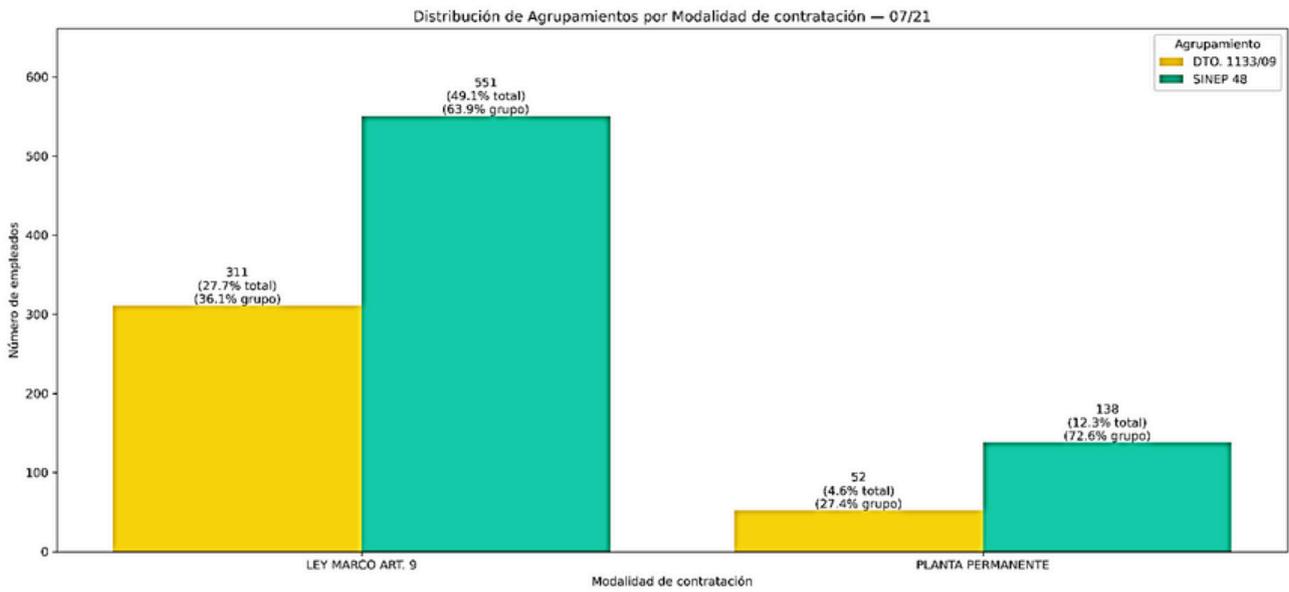


CHART: STAFF DISTRIBUTION BY GROUPING AND CONTRACTING METHOD



Clarification: In the graph where it says "grouping", there is a typo and it should be interpreted as SINEP, without taking into account the contracting modality which is what is shown in the bars and is identified for each sectoral agreement.

CHART BY CONTRACTING METHOD

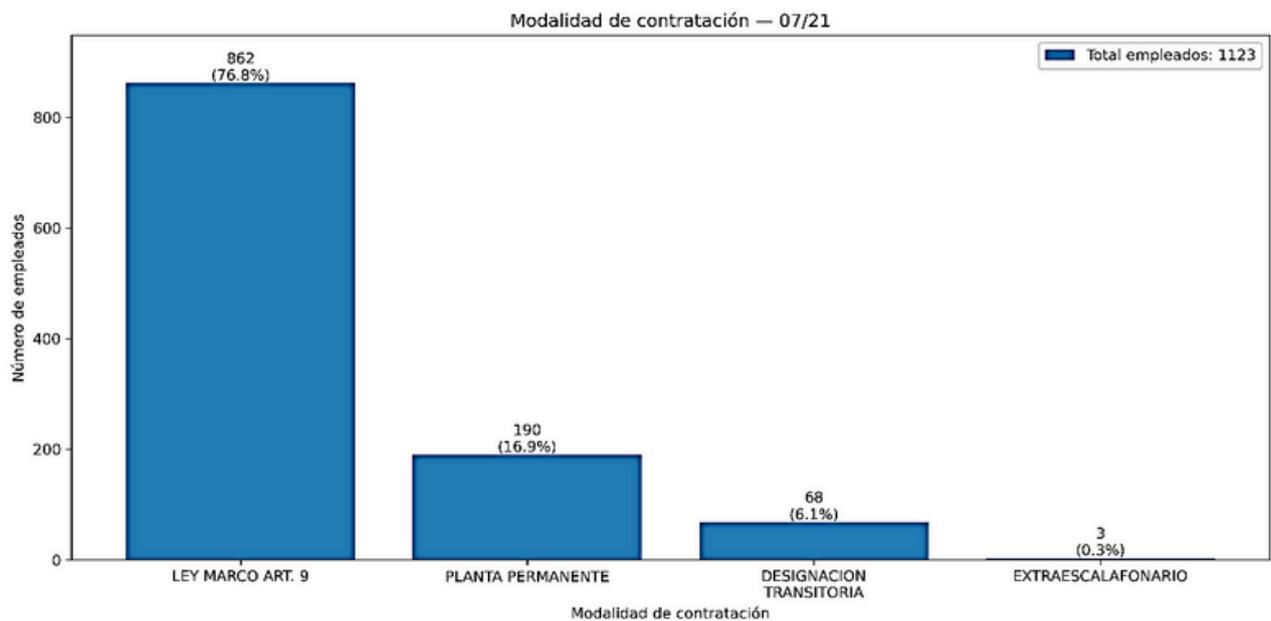
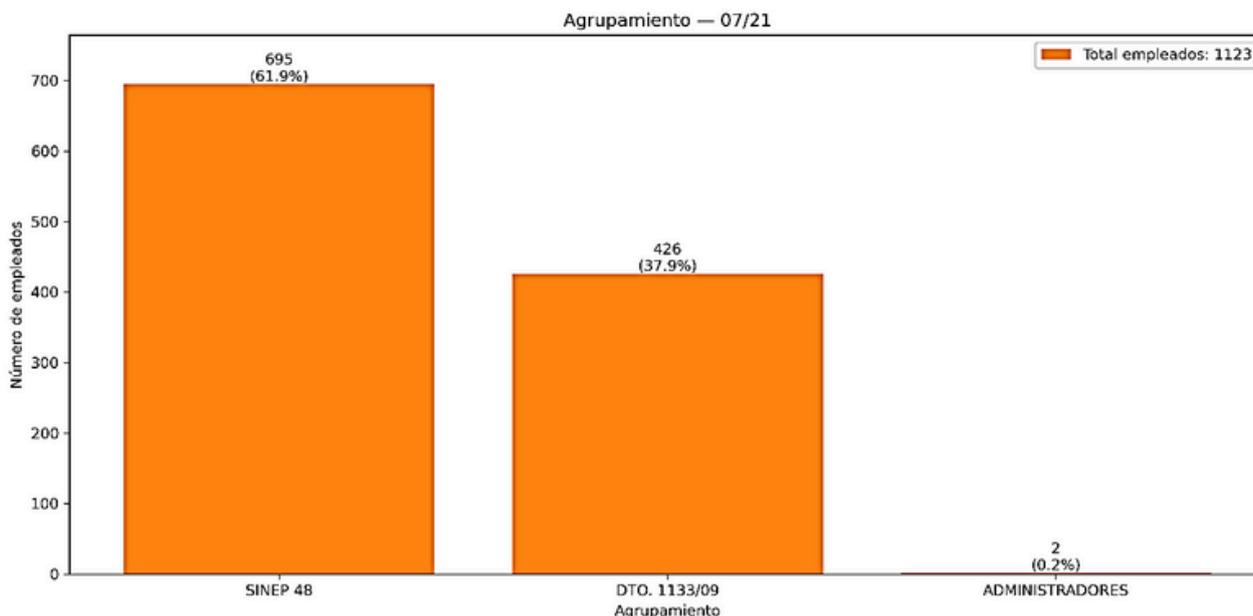


CHART BY CCTS/GROUPING



head of SSCE department and second wife of Daniel Gollán , continues at INAME)

2010-2015 Marta Spinetto

1993-2010 Carlos Chial

Department of Substances Subject to Special Control 2015 to present Andrea Rey (Rodolfo Lede 's wife)

It's worth noting that family and friendship ties exist and have existed among some officials in key administrative positions, which is why, among other things, nepotism is discussed at ANMAT. Children, spouses, lovers, siblings, friends. Little can change with the same people as always.

Historical background.

Main actors and profiles, according to what was found in the media.

“Jorge Manuel Salinas, a businessman linked to the Apolo Laboratory between 2005 and 2012, was prosecuted for fraud against PAMI, along with other businessmen, for diverting more than 21 million pesos - about seven million dollars at the time - through fake invoices and irregular contracts.”

“During the explosion, Salinas was no longer formally the owner of Apolo, but his trajectory in the sector generated investigations for his previous role in asset stripping, tax evasion and opaque dealings, including connections with laboratories in Paraguay, a country from which he trafficked serum.”

“At that time, the role of the State was also investigated, regarding inspections and permits repeatedly violated by the company under Salinas's direction, including repeated closures.”

“Finally, the court reached financial settlements with the victims and suspended sentences for two defendants, while for three others, charges were dismissed through agreements. Prosecutor Jurado determined in the investigation that the boiler exploded “due to negligence and failure to comply with regulations and duties” by those responsible. Damián García, along with García Furfaro and Marcela Voza, were acquitted. Manager Marcelo Ferré and supervisor Jorge Gómez had to complete probation at a foundation in the city of San Nicolás: the Justicialist Party Museum.”

“Four years before the Apollo explosion, the company's workers reported that the serums produced at Alem 2900 “did not comply with the quarantine periods required before their sale.”

“The partner of the García Furfaro and Salinas families was Mario Segovia, linked to the Pharmaceutical Mafia. Let us remember that Segovia started as a waiter at the Provincial Club in Rosario and in 10 years became the King of Ephedrine.”

“Salinas owned the Rigezin laboratory , which also specialized in the manufacture of serums. Following the acquisition of Apolo, its main competitor, this group gained control of more than half of the market for the supply of physiological serums. The main buyer, as

admitted by Deputy Graciela Ocaña, was PAMI at that time.”

They were part of the delegation to Russia, headed by former Health Secretary Carla Vizzotti , to bring the Sputnik V vaccine to Argentina during the Covid-19 pandemic. Other INAME officials also traveled: Inés Rizzo and Gladys Raquel Méndez.

November 2015 Apolo SA Laboratory Closed. Continues operating despite the measure. Salinas, Ariel and Damián García, owners and senior managers.

April 2016 Apolo Laboratory files for bankruptcy

June 2016 A boiler explodes in the laboratory

In July 2017, Ariel García Furfaro and Jorge Salinas acquired HLB from Hernán López Bernabó . It was then renamed HLB Pharma. Group .

Critical and Major Deviations detected from 2018 to 06-01-2025

2018 - Total 3

2019 - Total 20

2020 - Total 7

2021 - Total 14

2022 - Total 17

2023 - Total 24

2024 - Total 20

2025 - Total 1

Number of people dead to date: 174

On July 4, 2025, the newspaper La Nación published an article by Diego Cabot titled “Judges, Mayors, and Officials: The Incredible Network of Contacts of the Owners of the Deadly Fentanyl Lab and an Uncontrolled Business,” in which he argues that the HLB Pharma and Ramallo laboratories relied on an external protection scheme. This extensive and well-oiled network of political and judicial contacts makes it difficult to determine the role of each link. Some helped avoid inspections, others prevented the closure of the companies, and still others secured government contracts. This is how they operated in the shadows for years. The judicial investigation is now also focusing on the diversion of drugs to the illegal market.

Furfaro 's contacts and identified as a partner of a Chinese man in a drugstore, in addition to frequenting the country house with people related to the subject.

He also had ties to Freddy Lijo, the judge's brother, with whom he shared a passion for horse racing and the racetrack's business dealings at the San Isidro Racetrack. The article states that: "they even went so far as to provide free medication to visitors..." Several questions arise from this information. What medications were

being distributed? How did they find out about the inspections? Where did the tip-off come from?

Andrés Rodríguez, "El Centauro," deputy secretary general of the CGT (General Confederation of Labor), also shares a passion for horse riding and business. A member of the Jockey Club, he visited ANMAT (National Administration of Drugs, Food and Medical Technology) on June 3rd, just days before the impending health catastrophe. His union receives the "solidarity contribution"—a mandatory contribution—from state workers for "enjoying the benefits of collective bargaining." The National Constitution and International Treaties on employment recognize Freedom of Association, which is expressed in the worker's right to choose whether or not to join a union. Record of the visit to ANMAT: <https://www.facebook.com/watch/?v=1228249272183997>;

https://www.instagram.com/reel/DKck0OuxOgW/?utm_source=ig_web_copy_link

A year ago, the Unión Personal published a video defending ANMAT and responding to statements made by the Minister of Modernization, Federico Sturzenegger , entitled “ANMAT, PROUDLY OURS” <https://youtu.be/K61zmp9xFik?si=21880eHa8c8bC02y>. The first official whose duties have been restricted is Mariela García, wife of Diego Gueren, General Delegate of the UPCN Health Delegation. The measure was taken after Radio Rivadavia revealed in May that Mariela García received bribes in boxes of Vauquitas (a type of candy).

UPCN and various government administrations have inaugurated dining halls, exhibitions, and training programs, and have jointly signed agreements . https://www.upcndigital.org/capital/articulos/59407/catalogo_2023/catalogo_2023/politicas/formacion_sindical/304-Antolog%C3%ADadelBicentenario5.pdf ; <https://www.argentina.gob.ar/noticias/anmat-y-upcn-firman-convenio-para-implementar-el-programa-carpas-saludables> ;

<https://www.youtube.com/live/iBEMnIJ1NPM?si=xv11PZJCxO2EahfH>

<https://www.youtube.com/live/iBEMnIJ1NPM?si=B5GcSDmMn27EwyG4>

<https://www.instagram.com/p/C8KJzpUgecf/>

The García Furfaro family's connections transcended borders, establishing a laboratory in Brazil and another in the Triple Frontier, in Ciudad del Este, Republic of Paraguay.

The authorities of the Paraguayan Food and Drug Agency DINAVISA received advice on organizing and structuring the agency from former ANMAT authorities Valeria Garay and Carlos Chiale, former officials who, through their work, managed to celebrate exchange agreements, some in record time during this year.

2.d. Development of the current situation

The case of the contaminated fentanyl gained public attention on May 13th of this year, when the city of La Plata, in the province of Buenos Aires, became the center of a serious national health crisis following an outbreak of pneumonia that affected 18 patients in the intensive care unit of the Hospital Italiano and resulted in the death of nine of them, who had been given fentanyl contaminated with resistant bacteria manufactured by Laboratorios Ramallo SRL and distributed by HLB Pharma. Group SA

According to the report from the "National Pharmacovigilance System for the communication of quality deviations of ANMAT", the Italian Hospital of La Plata reported via email on 02/05/2025 (IF-2025-47591800-APN-INAME#ANMAT), the positive results for *Klebsiella pneumoniae* and *Ralstonia pickettii*, microorganisms that are not part of the hospital community and that from the analysis of the 18 cases they discovered that the affected patients had received the administration of Fentanyl HLB Pharma, at the request of the organization, on the 5th of the same month sends note detailing the event, the list of patients and indicating the deaths (IF-2025-46894706-APN-INAME#ANMAT), both reports belonging to EX -2025-46529833-APN-INAME-ANMAT.

On March 6, the use, marketing and distribution throughout the National territory is prohibited due to the market withdrawal of the product Propofol HLB 10 mg/ml injectable emulsion IV, lot 60000, expiry 30/09/2026 50 vials of 20 ml, Cert. No. 43.900" (anesthetic for intravenous use, was found on the market without the corresponding traceability label and without being registered in the Register of Medicinal Specialties).

On April 24, the use, marketing, and distribution throughout the national territory of the products "DICLOFENAC HLB / DICLOFENAC SODIUM, Certificate No. 52,922, lot 80020" and "MORPHINE 1% HLB / MORPHINE, Certificate No. 43,292, lot 31050" were prohibited. A market withdrawal order was issued.

On May 13, the Official Gazette published the

prohibition, use, distribution and marketing throughout the national territory of the product "FENTANYL HLB / FENTANYL CITRATE, concentration 0.05 mg/ml, in the pharmaceutical form injectable solution, 5 ml ampoule (presentation x 100 ampoules, according to VMN); lot 31202, expiration 09/26; Certificate No. 53,100" and ordered the firm HLB PHARMA GROUP SA (CUIT No. 30-70857859-9) to recall from the market the product "FENTANYL HLB / FENTANYL CITRATE, concentration 0.05 mg/ml, in the pharmaceutical form injectable solution, 5 ml ampoule (presentation x 100 ampoules, according to VMN); lot 31202, expiration 09/26; Certificate No. 53,100.

The situation becomes even more critical, given the numerous reports of serious adverse reactions and deaths associated -at least- with lot 31202 of FENTANYL HLB, facts that forced ANMAT to file the criminal complaint, the basis of the criminal case and the inhibition of the productive activities of the firms HLB PHARMA GROUP SA and LABORATORIOS RAMALLO SA. The magnitude, scope, and implications of the case in all its dimensions are still unknown, since, at the time of this report, November 2025, 174 deaths have been recorded, a number that remains open.

2.e. Variables adopted and argumentation

The selected variables arise from the elements to be compared based on the study topic, that is, the process of drug inspection and control, in particular the case of "Contaminated Fentanyl". These possible indicators were selected, among others, to evaluate and measure the function of the inspection of laboratories specializing in medicinal products, which are applicable to evaluate inspections carried out in other areas, for example Clinical Trials and Research and Biological Products, as well as those carried out in the other institutes that make up ANMAT, the National Institute of Medical Products (INPM), and the National Institute of Food INAL; in which the following activities are also monitored, controlled, supervised, certified and verified: international trade of import and export of raw materials, supplies, GMP, GMP, HACCP among others, preparation, fractionation, storage, marketing, distribution, surveillance, traceability and withdrawal from markets of cosmetic products, household cleaning products, food and all inspection processes whose purpose is to guarantee safety and protection of public health, in order to avoid causing very serious damage such as death, serious irreversible damage and other types of damage in which life is not

compromised.

The variables are based exclusively on academic sources and reliable regulatory agencies such as the WHO and the FDA, since ANMAT also follows the guidelines proposed by these agencies and internalizes them in the legal regime applicable to its responsibilities and competencies, in various ANMAT Provisions; which focus on solid theoretical data, such as guidelines for good laboratory practices, quality management systems and quality metrics.

After conducting a comparative evaluation of the proposed elements, the nine with the highest scores were selected. These can be grouped into the following categories: Operational Efficiency, Quality and Compliance, and Impact on Safety.

The selected ones are detailed below and subsequently a brief theoretical description is provided for each of them, applicable to the current legal regulatory framework, aligned with international standards.

1- NUMBER OF INSPECTORS :

There is no precise data on the number of inspectors that INAME has.

According to the list of inspectors published on the agency's website until July of this year, approximately 137 were listed (they were not numbered but listed by last name and first name); among which are counted all the professionals belonging to the INAME National Reference Laboratory, of which those who perform inspector functions are counted.

This number is significantly higher than the historical maximum of 30 professionals held by the INAME Inspection Department, before the separation of functions; which to date does not reach ten inspectors including the heads, and compared to the other areas of ANMAT, namely:

SSCE has 4 professionals.

INPM: 36 inspectors, of which there are professionals Decree No. 1133/09 and SINEP personnel with a secondary school diploma - commercial expert, that is, without technical training to carry out the inspection tasks.

Directorate of Evaluation and Management of Health Monitoring: 7

INAL: 10 including the head of the Sanitary Inspection Department.

2- NUMBER OF INSPECTIONS CARRIED OUT PER PERIOD:

No data available.

It measures regulatory coverage and the capacity for systematic monitoring of laboratories (operational efficiency), aligned with the planning of assessments in the instruments for laboratory oversight, based on potential risk. Scheduled inspections result from a combination of strategic guidelines and resource availability. The main aspects to consider in this scheduling are the need for periodic inspections (otherwise, interventions limited to occasional visits would be insufficient, as they may arrive too late), the consideration of hazard analyses related to the process and/or product use, the estimation and availability of resources, etc. Thus, the operational area proposes a list of establishments to be inspected to higher authorities, and the higher authority (National Directorate) ultimately decides which establishments will be inspected.

3- RESPONSE TIME TO CRITICAL NON-COMPLIANCE FINDINGS (DAYS FOR CORRECTION):

No data available.

Evaluate the agility in resolving non-conformities (non-compliance/deviations) based on the monitoring of quality indicators for continuous improvement in the Quality Management System

4- PERCENTAGE OF NON-COMPLIANCES/NC DETECTED BY INSPECTION:

No data available

It quantifies deviations from Good Laboratory Practices (GLP/GMP), derived from the analysis of observations during pharmaceutical inspections. The deviation is related to the assigned risk and the frequency with which it occurs. These are activities or processes that can result in immediate and concrete harm to consumer health. It is assumed that if the regulated sector complies with safety and quality standards, the rate of non-compliance detected by inspections, alerts, deviations, and market recalls are minimized.

5- PERCENTAGE OF MARKET WITHDRAWALS OR POST-INSPECTION ALERTS DUE TO CRITICAL DEVIATIONS.

No data available.

It assesses the preventive impact of inspections in the supply chain, linked to monitoring quality deviations.

ELEMENTOS A EVALUAR COMPARATIVAMENTE

Fiscalización y Control de Medicamentos. El caso del Fentanilo contaminado.

Use esta plantilla para comparar elementos entre sí y a cada uno de ellos con relación al tema de estudio. Puede usar la plantilla para calificar con uno, dos o tres criterios de evaluación la lista de elementos. Seleccione siempre los de mayor puntaje.

Nº	Lista de elementos a comparar	Importancia	Influencia sobre las demas	Pertinencia	Puntaje General
1	Número de laboratorios farmacéuticos	3	3	1	2,333333333
2	Número de laboratorios fabricantes de SSCE	5	5	1	3,666666667
3	Número de importadores de SSCE	5	2	1	2,666666667
4	Número de inspectores	5	5	5	5
5	Número de inspecciones realizadas por período	5	5	5	5
6	Tiempo promedio de respuesta a hallazgos críticos de incumplimiento (días para la corrección)	4	4	5	4,333333333
7	Porcentaje de laboratorios inspeccionados en función del riesgo	5	4	2	3,666666667
8	Tasa de Incumplimientos/NC detectados por inspección	2	2	4	2,666666667
9	Porcentaje de inspecciones con Desvíos Críticos detectadas por inspección (% de observaciones)	4	4	5	4,333333333
10	Porcentaje de inspecciones con Desvío mayor detectadas por inspección (% de observaciones)	3	4	5	4
11	Porcentaje de inspecciones con clasificación favorable (cumplimiento de la normativa)	2	1	1	1,333333333
12	Porcentaje de retiros de mercado o alertas post inspección por Desvíos Críticos de Calidad	5	4	5	4,666666667
13	Tiempo promedio de respuesta al Recupero de Mercado	4	4	5	4,333333333
14	Tasa de Invalidación de Fuera de Especificación (% justificados vs NC)	5	4	5	4,666666667
15	Cobertura de validación de métodos analíticos (% de equipos calibrados)	5	1	5	3,666666667
16	Número de resultados Fuera de Especificación (OOS) por lote analizado en los laboratorios	4	3	3	3,333333333
17	Tasa de Actos Administrativos con sanción por faltas sanitarias por incumplimientos con la normativa	4	4	5	4,333333333
18	inspecciones programadas no realizadas	5	3	5	4,333333333
19					0

Codigo	Factores Nombre	Coordenadas de		Ranking Estratégico
		Motricidad (y)	Dependencia (x)	
1	Nº DE INSPECTORES	16,00	16,00	A
2	Nº DE INSPECCIONES REALIZADAS POR PERÍODO	28,00	28,00	B
3	TIEMPO PROMEDIO DE RESPUESTA A HALLAZGOS	25,00	25,00	C
4	PORCENTAJE DE INSPECCIONES CON DESVÍOS	31,00	31,00	D
5	PORCENTAJE DE RETIROS DE MERCADO O ALERTAS	32,00	32,00	E
6	TIEMPO DE PROMEDIO DE RESPUESTA AL RECUPERO	21,00	21,00	F
7	TASA DE INVALIDACION DE FUERA DE ESPECIFICACIÓN	26,00	26,00	G
8	TASA DE ACTOS ADMINISTRATIVOS CON SANCIÓN POR	28,00	28,00	H
9	INSPECCIONES PROGRAMADAS NO REALIZADAS	29,00	29,00	I

taken (closure, seizure of goods, injunctions, market recovery, etc.), must be forwarded to the Legal Affairs Department within 24, 48, or 72 hours, depending on the severity of the sanction. This will activate the administrative process to ratify or rectify the preventive measures imposed to avoid potential risks and safeguard public health and safety. Laboratories with a history of sanctions will not be permitted to participate in public bidding processes or submit bids.

9- SCHEDULED INSPECTIONS NOT CARRIED OUT:

No data available.

Scheduled inspections not carried out are inspections that were planned but not carried out for various reasons, for example, because they were removed/crossed out by higher authorities from the proposed list of planned inspections for the period.

2.f. Trend, optimal and exploratory scenarios (if developed)

Since the data needed to perform the scenarios is not available from open sources, it is not possible to continue with the analysis method.

2.g. Risks and Opportunities of at least the trend scenario

Having carried out a survey and study of the reports of the Internal Audit Unit, the General Audit Office of the Nation and the report of the Public Prosecutor's Office exp PIA 337/2025 criminal file no. FLP 17371/2025 (Coirón 90994/2025), from the registry of the Federal Criminal and Correctional Court No. 3, Secretariat No. 8 of La Plata, the most important possible causes are indicated which, due to their structural nature, become the roots of the problem; those that resulted in this breaking event.

The PIA report states: "The recurrence of critical deviations in high-risk sterile products, coupled with the persistence of regulatory incidents (unauthorized packaging, inconsistent labeling, a case of marketing without a valid license), may constitute—in the fiscal hypothesis—a relevant indication to analyze the possible lack of diligence in the prevention and management of risks already identified by the health authority...".

"... The recurrence of serious findings over time, even in the face of previous regulatory measures, suggests the existence of structural deficiencies in the control and

prevention mechanisms, the understanding of which is key to assessing the health risk involved and its potential legal-criminal significance...".

"... The inefficiency of the regulatory measures ordered by ANMAT placed the population in an unacceptable risk situation, damaged the legitimate trust of users of the health system, affecting at the same time the proper functioning of the drug market and violating the constitutional mandate of protection of public health, established in art. 42 and 75 inc. 22 of the National Constitution...".

Finally, it argues that: "... The sum of these irregularities and deficiencies - whether intentional or negligent - together with the inadequacy of the regulatory actions that would have been implemented, seriously compromised health safety and generated an impermissible risk of criminal relevance...".

Computer systems used by the various departments that make up ANMAT, namely:

- *National Institute of Medicines*
- *National Institute of Medical Products*
- *National Institute of Food*
- *General Directorate of Administration*
- *Directorate of Evaluation and Management of Health Product Monitoring*
- *Technical Management Directorate*
- *Legal Affairs Department*
- *Human Resources Department*
- *Directorate of Institutional Relations*
- *The following describes the computer systems in production:*
- *National Drug Vademecum (VNM): It is a drug database of the ANMAT with data of a public nature and belonging to the Administration.*
- *National Drug Traceability System: consists of the individual and unique identification of each unit of the medicinal specialties to be marketed.*
- *National System of Traceability of Medical Products: consists of the individual and unique identification of each unit of medical product released to the market.*
- *Sly Actor: Evaluation and Registration System for Medicinal Specialties for Art. 5 of Decree 150/92. (Imaging System).*
- *REM: System for Evaluation and Registration of Medicinal Specialties for Articles 3 and 4 of Decree 150/92, suitable for Digital Signature.*
- *SIFEGA: Federal Information System for Food*

Control Management

- *Grade I Cosmetic Products System suitable for Digital Signature: Registers the registration of Grade I cosmetics.*
- *ECLIN: Clinical Pharmacology Study System suitable for Digital Signature:*
- *Inspection Order System: Generation of inspection orders for the different categories of ANMAT.*
- *Pharmacovigilance System : Online Reports for notifications of Adverse Reactions, from Patients, Healthcare Professionals and TARC Laboratories.*
- *VigiFlow System : used for managing the incorporation of information into the global database VigiBase . Developed by the WHO.*
- *GEMHA: Registry of authorizations of medical product establishments.*
- *HELENA: Medical Product Registration System. Registration, Modification and Renewal of Class I, II, III and IV Medical Products.*
- *COMEX: System for importing medical products.*
- *RAEM: Exceptional access regime to medicines (Compassionate Use).*
- *NDS System: import and export procedures for substances subject to special control. Developed by the UN.*
- *PEN Online System: Export procedures for chemical precursors. Developed by the UN.*
- *Electronic fee collection system.*
- *Treasury System: Collects fees less than \$300.*
- *System of Sworn Statements for the Registration of Medicinal Specialties.*
- *System of Sworn Statements for Registration of Medical Products.*
- *File System: Records the movement of files within the administration.*
- *Labeling System : Automatic labeling of paper files at the different reception desks.*
- *Simple Actions System: Labeling of simple actions at the Reception Desks.*
- *GDE.*
- *TAD.*
- *Fines System:*
- *E – SIDIF:*
- *COMPR.AR.*
- *System for Registering Domestic Trade Operations of Substances Subject to Special Controls:*
- *GEDO Viewer: It is used by Customs to verify that the paper documentation presented is a true copy of the procedures carried out remotely.*

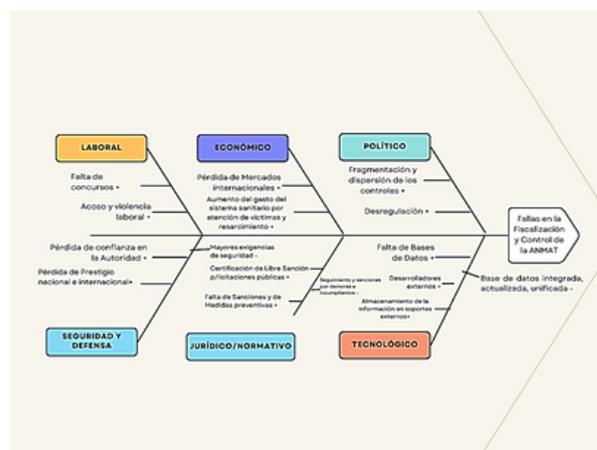
- *TABLEAU: GDE reporting tool.*
- *Tango System – Salaries and Wages Module:*
- *Time Control System.*

The absence of a secure, comprehensive, and accessible database represents a lost opportunity in terms of having real-time statistics and reliable information, integration and interaction of the various actors involved in the processes of registration, evaluation, auditing, monitoring, and control, thus optimizing the speed of the study of the files processed by the administration in its different institutes and areas.

Furthermore, the lack of human resources with specific technical training for the processing of the procedures leads to excessive delays in the evaluation of the procedures, in the planning of the inspections, in the results of the inspections, as well as in compliance with the deadlines set out in the regulations regarding the renewal of Certificates of Good Distribution Practices, impacting the safety and effectiveness of the process.

The audit reports reviewed in this investigation show that issues related to databases, processes, information, integration and interaction in databases and systems of all actors involved in the processes, with the aim of making the processes more efficient and secure and reliable, have been systematically delayed for at least the last 16 years.

Ishikawa Diagram attached.



3. CONCLUSIONS

The proposed techniques allow for systematizing and classifying information, selecting variables, and breaking down causes to reach the root of the problem. You can have the best organizational structures, but within them men and women bring their passions, their flaws and their virtues, and then the organization

changes.

In general terms, the obstacles encountered in carrying out this work were the absence of open data, since it was not possible to access sensitive information from the administration to complete the trend, current and optimal scenarios and the SATs.

If the necessary data for the selected indicators were available, the advantages of the applied analysis method could be fully leveraged, offering an anticipatory and continuous strategic analysis that attempts to improve the organization's current critical state, so that it can comply with the constitutional mandate to protect public health.

Finally, I would like to conclude this work with a quote from a speech to senior government officials that says:

“Consequently, if we share and distribute that responsibility among all of us, we all have the obligation to work to prevent this from happening within the public administration, in order to protect not only the prestige of the administration, but also the prestige of each one of us.”

CONCLUSION:

Analyst to Decision-Maker Report

The analysis team reports that it was able to conduct a partial analysis of the case, identify and characterize actors and interested third parties, search, select and classify information from open sources, academic sources, internal and external government control bodies, social networks, media, compare elements of the case, define variables and establish indicators to evaluate the SSCE's audit management, but lacks data for the analysis and development of historical, current, trend and optimal scenarios and an early warning system.

The absence of a comprehensive, unified, updated, integrated database available to the different actors involved in the processes, and the over-dimensioning of the organizational structure, among other causes, do not provide all the needs and functionalities required by the technical areas of ANMAT for registration, surveillance, inspection, control and monitoring, in order to facilitate the integration and interaction of the sectors, the organizational speed and the economy of the processes and to obtain statistical information for real-time decision-making.

The agency's sustained lack of diligence in complying with the observations of the control bodies

demonstrates structural deficiencies in the control and prevention mechanisms, which made it possible to place the population in an unacceptable risk situation, as the PIA maintains, damaging the trust of society and users and violating the constitutional mandate of protecting public health.

With the necessary data from the selected indicators, the advantages of the applied analysis method could be fully leveraged, offering proactive and continuous strategic analysis aimed at improving the organization's current critical state, enabling it to fulfill its constitutional mandate to protect public health.

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https://www.agn.gob.ar/sites/default/files/informes/2007_163_Informe.pdf

https://www.agn.gob.ar/sites/default/files/informes/2008_150info_0.pdf

https://www.agn.gob.ar/sites/default/files/informes/Informe_229_2012.pdf

https://www.agn.gob.ar/sites/default/files/informes/Informe_253_2013.pdf

<https://www.agn.gob.ar/sites/default/files/informes/2020-141-Informe.pdf>

<https://www.agn.gob.ar/sites/default/files/informes/2021-077-Informe.pdf>

<https://www.agn.gob.ar/sites/default/files/informes/2021-116-Informe.pdf>

<https://www.sigen.gob.ar/archivoweb/Buscador.aspx>

<https://www.argentina.gob.ar/anmat/regulados/resultados-de-inspecciones-de-buenas-practicas-clinicas>

Quarterly Report Chemical Precursors Form <https://tramitesadistancia.gob.ar/tramitesadistancia/detalle-tipo?id=1412>

Notice of Destruction of Substances Subject to Special Control <https://www.argentina.gob.ar/servicio/destruccion-de-drogas-solicitud-del-interesado>

Application for Free Sanction of Establishments

<https://tramitesadistancia.gob.ar/tramitesadistancia/detalle-tipo?id=4840>

Requirements for applying for an ANMAT Certificate of Free Sanction

<https://tramitesadistancia.gob.ar/tramitesadistancia/detalle-tipo?id=2699>

Traceability, benefits https://www.argentina.gob.ar/sites/default/files/anmat_certificado_de_libre_circulacion_instructivo.pdf

<https://www.argentina.gob.ar/justicia/derechofacil/leysimple/trazabilidad-de-medicamentos#titulo-1>

<https://www.cafabo.org.ar/main/noticias-ver/anmat-cambios-y-renovacion-/>

<https://www.enredando.org.ar/2016/07/07/laboratorio-apollo-tablada-se-organiza-para-conocer-causas-y-responsables/> YEAR 2012

12/17 ANMAT created a directorate for the control of biotechnological medicines and established a working group for food regulation

<https://bfbdigital.org.ar/index.php/2012/12/17/la-anmat-creo-una-direction-para-el-control-de-medicamentos-biotecnologicos-y-se-establecio-una-de-trabajo-para-regulation-de-alimentos/>

YEAR 2014

15/09 ELECTRONIC MANAGEMENT SYSTEM WITH DIGITAL SIGNATURE. ANMAT. The ELECTRONIC MANAGEMENT SYSTEM WITH DIGITAL SIGNATURE is adopted for the procedure of APPLICATION FOR REGISTRATION IN THE REGISTER OF MEDICINAL SPECIALTIES (REM) framed in article 4 of Decree No. 150/92 (to . 1993) for active pharmaceutical ingredients (APIs) of synthetic and semi-synthetic origin . Provision 6428/2014.

https://www.cda.org.ar/detalle_noticia.php?id=26727

YEAR 2015

17/04 Surar Pharma , closed

<https://www.pharmabiz.net/surar-pharma-clausurado/> <https://www.pharmabiz.net/wp-content/uploads/2015/04/dispo2.pdf> ANMAT Resolution on Closure December 2015 ANMAT: 2016 team confirmed. ANMAT head Carlos Chiale finalized his team. <https://www.pharmabiz.net/anmat-equipo-2016-confirmado/> YEAR 2016 03/08 An Apolo shareholder is now opening a new laboratory in Ramallo. Residents near the damaged plant had reported that the local stock was being moved to that district in Buenos Aires province.

<https://www.lacapital.com.ar/la-ciudad/un-accionista-apollo-abre-ahora-un-nuevo-laboratorio-ramallo-n1201912.html>
YEAR 2017

On July 11th, HLB Pharma changed hands. Although the transfer has not been officially formalized, the new owners are Ariel García Furfaro and Jorge Salinas, owners of the Ramallo and Apolo laboratories. <https://www.pharmabiz.net/hlb-con-nuevo-dueno/> YEAR 2018 26/03 MARKET WITHDRAWAL OF A BATCH OF THE PRODUCT DIPYRONE 2.5 G https://www.pharmabiz.net/wpcontent/uploads/2018/03/Dipirona_retiro_Lab_Ramallo_26-03-18.pdf 26/03 MARKET WITHDRAWAL OF A BATCH OF THE PRODUCT LIDOCAINE SOLUTION 1% https://www.pharmabiz.net/wpcontent/uploads/2018/03/Lidocaina_retiro_Lab_Ramallo_26-03-18.pdf 28/03 ANMAT: withdrawal for Ramallo. According to qualified sources consulted by Pharmabiz , the low prices of the Ramallo laboratory are plausible because its production standards are below the requirements. <https://www.pharmabiz.net/anmat-retiro-para-ramallo/> YEAR 2019 In April 2019, ANMAT met with representatives of a Russian health institution. Those participating in the meeting on behalf of ANMAT included the National Administrator, Carlos Chiale , and the Director of Inspection and Risk Management of INAME-ANMAT, Matías Gómez. <https://www.argentina.gob.ar/noticias/anmat-se-reunio-con-representantes-de-institucion-sanitaria-de-rusia>

ELCANO INSTITUTE

https://media.realinstitutoelcano.org/wp-content/uploads/2021/11/ari122-2019-estado-y-crimen-mercado-ilegal-efedrina-en-argentina-2003-2018.pdf?_gl=1*2mp5oh*_ga*NDgwMDM3MzQ5LjE3NjE3NjY5NzA.*_ga_DR7R0Z3Q4L*cze3NjE4NTQ2NzUkbzlkZzZkdDE3NjE4NTQ2NzUkajYwJGwwJGgw

12/09 ARGENTINA.GOB.AR

The use of the "Federal Voucher" for the management of opioid medications was approved.

<https://www.argentina.gob.ar/noticias/se-aprobo-el-uso-del-vale-federal-para-la-gestion-de-los-medicamentos-opioides>
YEAR 2020

July 15th: Recall of a batch of Ringer's Lactate solution from the Ramallo laboratory. The product is used as a regulator of fluid and electrolyte balance.

<https://www.argentina.gob.ar/noticias/retiro-del-mercado-de-un-lote-de-solucion-ringer-con-lactato-del-laboratorio-ramallo>

YEAR 2022

17/01 Provision 476/2022 DI-2022-476-APN-ANMAT#MS Communication of adverse events issued by the College of Pharmacists of the Province of Buenos Aires, who reported that, from the pharmacy of a Hospital in the Province of Buenos Aires, they detected in one of the ampoules of the product HLB DISTILLED WATER (water for injection) Lot 30250 Exp : 05/2023, from the laboratory HLB PHARMA GROUP SA, particulate matter , therefore not complying with the Argentine Pharmacopoeia

<https://www.boletinoficial.gob.ar/detalleAviso/primera/256357/20220120>

28/01 Market withdrawal of a batch of the product HLB Distilled Water. This product is used as a diluent.

<https://www.argentina.gob.ar/noticias/retiro-del-mercado-de-un-lote-del-producto-agua-destilada-hlb> 15-02 Ministry of Health of Santa Fe <https://www.santafe.gov.ar/index.php/web/content/download/266748/1394894/file/Alerta%2002%2022.pdf>

2-/04 Market withdrawal of a batch of Metronidazole Ramallo. The measure was taken due to the discovery of possible microbial contamination.

<https://www.argentina.gob.ar/noticias/retiro-del-mercado-de-un-lote-de-metronidazol-ramallo>

In February 2022, an OAS report and two DEA reports warned of increased fentanyl use in Argentina. Aníbal Fernández and Patricia Bullrich engaged in a heated debate regarding this case and the analysis of these reports, arguing for increased controls to prevent this legal drug from entering the illicit market.

https://www.clarin.com/politica/informe-oea-dea-alertaron-aumento-consumo-fentanilo-argentina_0_ikhFg7dtv6.html

YEAR 2023

19/05/ Recall of a batch of ROLFITA

The measure was taken after out-of-specification results were obtained for hardness and friability tests.

<https://www.argentina.gob.ar/noticias/retiro-del-mercado-de-un-lote-de-rolfita>

28/09 Argentine Customs tightened controls against fentanyl , the deadly drug that is spreading from China.

<https://www.infobae.com/politica/2023/09/29/la-aduana-argentina-endurecio-los-controles-contr-el-fentanilo-la-droga-mortal-que-avanza-desde-china/> YEAR 2024 25/10 COLFARMA ALERT FROM THE RPVF: Products from the firm HLB

Pharma , cosmetics and food Market withdrawal of a batch of Diclofenac HLB and a batch of Morphine 1% HLB

<https://www.colfarma.info/colfarma/alerta-de-la-rpvf-productos-de-la-firma-hlb-pharma-cosmeticos-y-alimenticios/> October 25th: Market withdrawal of one batch of Diclofenac HLB and one batch of Morphine 1% HLB. The measure was taken after the detection of secondary packaging labeled as "Morphine 1% HLB" but containing ampoules of the product "Diclofenac HLB".

<https://www.argentina.gob.ar/noticias/r-retirement-of-the-market-of-a-lot-of-diclofenac-hlb-and-of-a-lot-of-morphina-al-1-hlb> YEAR 2025 24/02 Warnings for non-compliance with Good Manufacturing Practices at LABORATORIOS RAMALLO SA The National Institute of Medicines carried out an inspection at the establishment following several reports under suspicion of non-compliance with Good Manufacturing Practices (GMP).

<https://www.argentina.gob.ar/noticias/advertencias-por-incumplimiento-de-buenas-practicas-de-fabricacion-en-laboratorios-ramallo> 28/02 That the aforementioned proceedings were initiated following a notification received regarding the suspicion of an illegitimate or counterfeit product, given that they had received the product labeled as "Dopamine HLB, dopamine hydrochloride 40 mg/ml IV injectable, LOT 31214, EXP. OCT26, 100 ampoules of 5 ml, Cert . No. 43.125" without the corresponding traceability label. Ownership by the company SURAR PHARMA SA

<https://www.boletinoficial.gob.ar/detalleAviso/primera/322188/20250306> March 7th: Ramallo flagged red by ANMAT (National Administration of Drugs, Food and Medical Technology). <https://www.pharmabiz.net/ramallo-con-bandera-roja-de-la-anmat/16/04> ANMAT orders HLB PHARMA GROUP SA to withdraw all batches of the product " Propofol HLB" from the market

<https://www.argentina.gob.ar/noticias/se-ordena-la-firma-hlb-pharma-group-sa-el-retiro-del-mercado-de-todos-los-lotes-del>

17/04 PHARMABIZ HLB Pharma adds another ANMAT recall

<https://www.pharmabiz.net/hlb-pharma-suma-otro-recall-de-anmat/>

04/18 BO Provision 2569/2025 DI-2025-2569-APN-ANMAT#MS

April 24, Page 12: ANMAT (National Administration of Drugs, Food and Medical Technology) has banned the sale of a commonly used anti-inflammatory drug. The measure was taken due to a cross-contamination incident, which poses a risk to public health.

<https://www.pagina12.com.ar/820599-la-anmat-prohibio-la-venta-de-un-medicamento-antiinflamatori>

April 28, EL CRONISTA: The sale of this popular medication has been banned and its urgent removal from all pharmacies has been demanded due to health risks. The regulatory agency prohibited the sale of two drugs due to "cross-contamination."

<https://www.cronista.com/informacion-gral/prohiben-la-venta-y-exigen-el-retiro-urgente-de-este-popular-medicamento-de-todas-las-farmacias-por-ser-peligrosoparalasalud/>

29/04 OFFICIAL BULLETIN resigned from his position as Director: Hugo Orlando Suarez Borello , Damián Roberto García was appointed in his place.

<https://www.boletinoficial.gob.ar/pdf/linkQR/RCszM01XNzhBbForeFpJZ1U0d1UwZz09> 11/05 ANMAT Resolution 3156/2025 Prohibition of Fentanyl Use and Market Recovery <https://www.boletinoficial.gob.ar/web/utills/pdfView?file=%2Fpdf%2Faviso%2Fprimera%2F325221%2F20250513>

TUESDAY, MAY 13 ANMAT STATEMENT <https://www.argentina.gob.ar/noticias/anmat-informa-que-se-inhiben-las-actividades-productivas-de-la-firma-hlb-pharma-group-sa>

12:20 ARGENTINE NEWS NA Ramallo Laboratories has banned production of a drug that allegedly caused pneumonia in 18 patients. It is part of HLB Pharma. A group owned by businessmen Ariel García Furfaro and Jorge Salinas. During the pandemic, they distributed the Russian Sputnik vaccine .

https://noticiasargentinas.com/politica/prohiben-la-produccion-de-laboratorios-ramallo-por-un-medicamento-que-habria-causado-neumonia-a-18pacientes_a68235e65bbc030e655828442?srsltid=AfmBOoqhKikEQAKLdda

ANMAT will inhibit HLB Pharma The Group is being investigated for "serious irregularities" in its products and will file a criminal complaint. The National Administration of Drugs , Food and Medical

Technology (ANMAT) will order the suspension of the HLB Pharma laboratory Group SA due to "serious and repeated irregularities" in the quality and traceability of its products. They will also be filing a criminal complaint. <https://www.ambito.com/informacion-general/anmat-inhibira-hlb-pharma-group-graves-irregularidades-sus-productos-y-presentara-una-denuncia-penal-n6144445> 13/05 EL DÍA. <https://www.eldia.com/nota/2025-5-13-11-49-0-investigacion-9-muertes-en-el-hospital-italiano-de-la-plata-por-fentanilo-contaminado-la-ciudad> <https://www.eldia.com/nota/2025-5-13-11-49-0-investigacion-9-muertes-en-el-hospital-italiano-de-la-plata-por-fentanilo-contaminado-la-ciudad> <https://www.infobae.com/politica/2025/05/13/vinculan-la-muerte-de-9-pacientes-con-el-fentanilo-elaborado-por-un-laboratorio-que-fue-clausurado-por-la-anmat/>

La Plata: 9 dead from the use of fentanyl contaminated with bacteria

Half of the 18 infected patients in Buenos Aires province have died. ANMAT has suspended HLB Pharma laboratory. Group , marketer of the ampoules, and Ramallo Laboratories, where they were produced.

<https://www.perfil.com/noticias/politica/la-plata-9-muertos-por-el-uso-de-fentanilo-contaminado-con-bacterias.phtml>
13/05 LA NACIÓN

Investigation: The alarming case of fentanyl contaminated with bacteria that allegedly caused nine deaths in a hospital. The Malbrán Institute is comparing samples to determine if its use caused 18 cases of severe pneumonia in an intensive care unit in La Plata.

<https://www.lanacion.com.ar/sociedad/investigacion-el-alarante-caso-del-fentanilo-contaminado-con-bacterias-que-habria-causado-nueve-nid13052025/>
13/05 INFOCIELO

Pharma products . ANMAT suspended HLB Pharma and Laboratorios Ramallo after an infectious outbreak that caused nine deaths at a hospital in La Plata.

<https://www.infocielo.com/politica-y-economia/tras-el-brote-fatal-en-la-plata-anmat-prohibio-todos-los-productos-de-hlb-pharma>
13/05 0221

The use of contaminated fentanyl is believed to have caused the deaths of nine people at the Italian Hospital in La Plata. Nine people died and nearly a dozen are hospitalized, suspected to be victims of contaminated fentanyl in hospitals in La Plata and Rosario.

<https://www.0221.com.ar/la-plata/el-uso-fentanilo-contaminado-habria-causado-la-muerte-nueve-personas-el-hospital-italiano-la-plata-n109594>
14/05 THE DAY

<https://www.eldia.com/nota/2025-5-14-12-46-0-muerte-por-fentanilo-contaminado-en-la-plata-paso-a-paso-como-actua-la-provincia-en-torno-al-brote-fatal-la-ciudad>

14/05 THE CAPITAL

Carina Bazzoni HLB Pharma : the laboratory that distributed contaminated fentanyl and its dark history in Rosario. Its owners were also the owners of Apolo, a laboratory that exploded ten years ago in Tablada, an incident that exposed a chain of irregularities. They later moved to Ramallo.

<https://www.lacapital.com.ar/la-ciudad/hlb-pharma-el-laboratorio-que-distribuyo-el-fentanilo-contaminado-y-su-oscura-historia-rosario-n10195902.html>

16/05 Public TV

La Plata: Nine deaths at the Italian Hospital are under investigation for the use of contaminated fentanyl . Suspicion has fallen on Ramallo Laboratories, located in the town of Ramallo in Buenos Aires province.

<https://www.tvpublica.com.ar/post/la-plata-investigacion-9-muertes-en-el-hospital-italiano-por-el-uso-de-fentanilo-contaminado>

May 20, INFOBAE: The government is investigating whether the laboratory that manufactured contaminated fentanyl diverted the opiate for illegal purposes. The Ministries of Security and Health are in charge. HLB Pharma and Laboratorio Ramallo are being investigated by Judge Ernesto Kreplak for the deaths of nine patients.

<https://www.infobae.com/politica/2025/06/21/fentanilo-contaminado-revelan-falencias-en-el-control-de-laboratorios-por-parte-de-la-anmat/>

21/05 EL PAÍS

Fourteen people have died and 50 others have been infected after being contaminated with fentanyl used in clinical settings in Argentina. Two bacteria that cause pneumonia were detected in one batch of the drug. Health authorities warn that there could be more victims.

<https://elpais.com/argentina/2025-05-21/mueren-14-personas-y-otras-50-resultan-infectadas-por-fentanilo-de-uso-clinico-contaminado-en-argentina.html>

26/05 ANMAT Press Release

<https://www.argentina.gob.ar/noticias/informacion-relacionada-con-los-productos-de-la-firma-hlb-pharma-group-sa>

JUNE

2/06 ARGENTINE NEWS HLB Pharma Scandal : Traceability Failures, Uninspected Fentanyl , Unused Software, and Political Connections. An audit revealed that fentanyl is not inspected in Argentina , nor are international control systems used. The case implicates officials and laboratories.

https://noticiasargentinas.com/politica/escandalo-hlb-pharma-fallas-en-trazabilidad-fentanilo-sin-inspeccion-software-sin-uso-y-vinculos-politicos_a683dfe5667cc4e971d2c9f5d

June 21st : Contaminated Fentanyl : ANMAT's Control of Pharmaceutical Laboratories in Argentina Revealed. The health tragedy unleashed by the use of adulterated fentanyl has raised serious concerns and brought the agency's oversight mechanisms into sharp focus.

<https://www.0221.com.ar/nacional/fentanilo-contaminado-revelan-fallas-el-control-la-anmat-los-laboratorios-farmaceuticos-argentina-n111610>

May 21 - Contaminated Fentanyl : ANMAT Reveals Deficiencies in Laboratory Control. The HLB Pharma case , linked to 40 deaths, exposes a lack of inspections and shortcomings in the traceability of controlled substances. An official acknowledges staff shortages and deficiencies in official audits.

<https://www.infobae.com/politica/2025/06/21/fentanilo-contaminado-revelan-falencias-en-el-control-de-laboratorios-por-part-de-la-anmat/>

Carlos Chiale , former head of ANMAT (National Administration of Drugs, Food and Medical Technology). Laxer regulations for low-risk medical supplies. ANMAT will stop authorizing imports, and there are concerns about post-entry controls. The new measure affects 70% of imported medical products.

<https://comunicar-salud.com.ar/nota/48422/regulacion-mas-laxa-en-insumos-medicos-de-bajo-riesgo/>

JULY

1/7 Deadly Fentanyl : The mysterious flights to Paraguay by the owner of HLB Pharma in private planes. Ariel García Furfaro has made more than 30 trips to that country since 2013. A third of them were in the last year and a half, according to data included in the court case. The clue of a factory in the Triple Frontier

<https://www.infobae.com/politica/2025/07/01/fentanilo-mortal-los-misteriosos-vuelos-a-paraguay-del-dueno-de-hlb-pharma-en-aviones-privados/>

July 16th URGENT 24 WHEN THE STATE FAILS. Rotten fentanyl exposes the corruption and negligence of ANMAT. Who at ANMAT authorized the purchase of fentanyl from HLB Pharma ? And who authorized its subsequent destruction ? ANMAT requires reform.

<https://urgente24.com/actualidad/el-fentanilo-pod-rido-expone-lacorrupcion-y-desidia-anmat-n605609>

ENCRYPTED DATA. The [fentanyl route](#) . García Furfaro , owner of HLB Pharma , imported 23% of the fentanyl used in the pharmaceutical industry.

<https://encripdata.com/2025/08/27/garcia-furfaro-hlb-pharma-importo-23-fentanilo-farmaceutica/>

ENCRYPTED DATA. [The fentanyl route](#) . Two medical representatives arrested for diverting more than 500 vials of fentanyl from hospitals.

<https://encripdata.com/2025/07/10/visitadores-medicos-desviar-mas-500-ampollas-fentanilo-misiones/>

12/07 LA NACION CABOT AND DOLBAJIAN

<https://www.lanacion.com.ar/politica/el-caso-del-fentanilo-mortal-estalla-en-paraguay-y-afecta-a-un-expresidente-ya-un-embajador-nid12072025/> AUGUST

04/08 Radio La RED Fernando Cardini, toxicologist: "By 2025 there shouldn't be any contaminated ampoules left"

<https://www.youtube.com/watch?v=v4PBzVPhFwU>

5/8 AMBITO Contaminated Fentanyl : The Ministry of Security filed a complaint against the HLB Pharma laboratory . The ministry, headed by Patricia Bullrich, accused the company of presenting a false authorization certificate to import opioids. The courts are investigating the deaths of 68 people.

<https://www.ambito.com/informacion-general/fentanilo-contaminado-el-ministerio-seguridad-denuncio-al-laboratorio-hlb-pharma-n6175114>

5/08 TN Carolina VILLALBA Contaminated Fentanyl : Investigation underway into whether the owner of HLB Pharma presented a falsified permit. García Furfaro was accused of falsifying a permit issued by the Municipality of San Isidro to import the opioid.

<https://tn.com.ar/policiales/2025/08/05/fentanilo-contaminado-investigacion-si-el-dueno-del-laboratorio-hlb-pharma-presento-una-habilitacion-falsa/>

5/08 MENDOZA The Government denounced the HLB Pharma laboratory for falsifying documents to import fentanyl

<https://www.mdzol.com/sociedad/el-gobierno-denuncio-al-laboratorio-hlb-pharma-falsificar-documentos-importar-fentanilo-n1307936>

6/08 PROFILE ANMAT denied that HLB Pharma is authorized to operate: the company remains barred from doing business by the courts. The agency denied that the laboratory under investigation for deaths caused by contaminated fentanyl can purchase certificates or produce medications.

<https://www.perfil.com/noticias/sociedad/la-anmat-autorizo-a-la-farmaceutica-apuntada-por-el-fentanilo-contaminado-a-adquirir-nuevas-licencias-de-medicamentos.phtml>

CLARÍN Fabián Debasa Now the government says that the HLB Pharma laboratory cannot manufacture or sell medications. ANMAT (National Administration of Drugs, Food and Medical Technology) stated that the company under investigation for the contaminated fentanyl is formally barred from doing business and has not been authorized to purchase drug certificates.

<https://www.elonce.com/sociedad/fentanilo-desmienten-que-hlb-pharma-este-habilitada.htm>

August 10, LA NACIÓN, DIEGO CABOT. Deadly Fentanyl : More plaintiffs join the case and a criminal investigation has been opened against the owners of HLB Pharma for operating illegally. The Ministry of Security has joined the case and accused the laboratory of presenting a false municipal certification; the Municipality of Rosario is also a plaintiff.

<https://www.lanacion.com.ar/economia/fentanilo-mortal-se-suman-querellantes-y-se-abrio-una-causa-penal-contra-los-duenos-de-hlb-pharma-nid09082025/>

12/08 EL PAÍS Diego Lorca At least 76 dead in Argentina from the use of contaminated clinical fentanyl . The courts confirm that there could be more victims and assure that ampoules of the opiate infected with bacteria are no longer circulating in health centers.

<https://elpais.com/argentina/2025-08-12/al-menos-76-muertos-en-argentina-por-el-uso-de-fentanilo-clinico-contaminado.html>

August 13th URGENT 24 Deadly Fentanyl : HLB Pharma washes its hands, speaks of sabotage, and points the finger at a former partner. The owner of the HLB Pharma laboratory questioned the theory of contaminated fentanyl and pointed the finger at a former partner with whom he had a falling out.

<https://urgente24.com/actualidad/sociedad/fentanilo-mortal-hlb-pharma-se-lava-las-manos-hablan-sabotaje-y-apuntan-un-ex-socio-n607519>

14/08 TN # TodoNoticias#TN #FENTANYL News : Reports that implicate HLB Pharma , the ministry's main supplier.

The government will recuse Judge Ernesto Kreplak from the case concerning the use of contaminated fentanyl . This recusal is based on his family ties to the Buenos Aires Province Health Minister, Nicolás Kreplak . HLB Pharma is the ministry's main supplier.

https://youtu.be/_snqf5_dBjs?si=atQPftGxwWm-gaO3

14/08 INFOBAE Andrés Klipphan

<https://www.infobae.com/politica/2025/08/14/the-owner-of-hlb-pharma-wanted-to-acquire-licenses-to-produce-more-medicines-and-presented-himself-as-the-one-who-killed-more-than-90-people/>

14/08 ABC CONTAMINATED FENTANYL. UNDERREPORTING AND CONNECTION WITH PARAGUAY

<https://www.abc.com.py/internacionales/2025/08/15/fentanilo-contaminado-hablan-de-posible-subregistros-de-muertes-en-argentina/>

15/08 <https://fmdelta903.com/programas/wakeup/59273-fernando-cardini-lo-del-fentanilo-contaminado-es-un-crimen>

15/08 LA NACION Press reader

https://www.pressreader.com/argentina/lanacion/20250815/28170262080238?srsltid=AfmBOoppPx_KMi7P0AyGoAXspfvTU2g0xp7henbEY7obcLM5wgnNeW

15/08/2025 LA NACION

<https://www.lanacion.com.ar/sociedad/quienes-son-las-responsables-de-la-anmat-que-quedaron-en-la-mira-del-gobierno-por-el-escandalo-delnid14082025/>

AUGUST LN FACEBOOK INTERVIEW CAMILA DOLBAJIAN

<https://www.facebook.com/reel/1280544459612025>

August 15th PROFILE The 26 questions the Government and ANMAT must answer about contaminated fentanyl . Members of the Social Action and Public Health Committee have requested information from the Executive Branch to establish the magnitude of the outbreak, identify the adulterated batches, and specify responsibilities.

<https://www.perfil.com/noticias/politica/las-26-preguntas-que-el-gobierno-y-anmat-deben-responder-sobre-el-fentanilo-contaminado.phtml>

19/08 # AllNews#TN#News

The courts are also investigating inconsistencies in the quantities of the substance found during two inspections. They suspect there was an intentional diversion to the illegal market. This is what HLB Pharma , the Furfaro laboratory from which the contaminated fentanyl originated, looks like inside.

<https://youtu.be/IYO4ADnEZOQ?si=LilXsVJdWGTb5n3>

19/09 Fentanyl under scrutiny: the importance of regulation and traceability. The HLB Pharma contaminated fentanyl case raised alarms in the healthcare system. Here are five key points to understand it and an urgent question: how should drug control work?

<https://canalabierto.com.ar/2025/08/19/fentanyl-under-the-microscope-the-importance-of-regulation-and-traceability/>

20/08 EL PAÍS Javier Lorca

<https://elpais.com/argentina/2025-08-21/detenidos-los-responsables-del-laboratorio-investigado-por-un-centenar-de-muertes-por-fentanilo-en-argentina.html>

The judge orders the arrest of the owners of HLB Pharma and Laboratorios Ramallo, the companies behind the contaminated clinical opiate.

21/08 UNNE Contaminated Fentanyl : "The laboratories involved have skipped all biosafety procedures"

<https://medios.unne.edu.ar/2025/08/21/fentanilo-contaminado-los-laboratorios-involucrados-se-han-saltado-todos-los-procesos-de-bioseguridad/> 21-08 PUBLIC PROSECUTOR'S OFFICE. Contaminated Fentanyl : The Public Prosecutor's Office

reports on the investigation that led to the arrest and questioning of directors and technical managers of the laboratories.

<https://www.mpf.gob.ar/pia/fentanilo-contaminado-el-mpf-informa-sobre-la-investigacion-que-derivo-en-la-detencion-e-indagatoria-de-directivos-y-responsables-tecnicos-de-los-laboratorios/> 23/08 RADIO RIVADAVIA GUADA RELOADED

Contaminated Fentanyl : The lack of controls at ANMAT was systematic. https://www.youtube.com/watch?v=yORDZ-J_M34

26-08 ENCRIPDATA The fentanyl route García Furfaro , owner of HLB Pharma , imported 23% of the fentanyl used in the pharmaceutical industry. <https://encripdata.com/2025/08/27/garcia-furfaro-hlb-pharma-importo-23-fentanilo-farmaceutica/>

26/08 MINUTE ONE

According to the owner of HLB Pharma , "someone put the bacteria" in the contaminated fentanyl .

<https://www.minutouno.com/sociedad/segun-el-dueno-hlb-pharma-alguien-me-tio-la-bacteria-el-fentanilo-contaminado-n6183031>

27/08 ENCRIPDATA. The [fentanyl route](#): García Furfaro , owner of HLB Pharma , imported 23% of the fentanyl used in the pharmaceutical industry

<https://encripdata.com/2025/08/27/garcia-furfaro-hlb-pharma-importo-23-fentanilo-farmaceutica/>

Cristina blamed Sturzenegger for the fentanyl deaths

August 28, 2025 Published by: [The Highlighter](#)

WHO ALERT No. 4/2025 on medical products. Substandard (contaminated) HLB FENTANYL (fentanyl citrate) detected in the WHO Region of the Americas

[https://www.who.int/es/news/item/29-08-2025-medical-product-alert-n-4-2025--substandard-\(contaminated\)-fentanyl-hlb-\(fentanyl-citrate\)](https://www.who.int/es/news/item/29-08-2025-medical-product-alert-n-4-2025--substandard-(contaminated)-fentanyl-hlb-(fentanyl-citrate)) https://cdn.who.int/media/docs/default-source/substandard-and-falsified/n4_2025_fentanyl_hlb_sp.pdf?sfvrsn=d1f750c8_6_30/08 CNN IN SPANISH Lack of controls, 10 arrested and almost 100 deaths: the contaminated fentanyl plot that scandalizes Argentina.

<https://cnnespanol.cnn.com/2025/08/30/argentina/fentanilo-contaminado-argentina-orix> 30/08 INFOBAE Andrés Klipphan <https://www.infobae.com/politica/2025/08/30/habia-ratas-y-la-gente-se-descomponia-por-el-calor-asi-producian-el-fentanilo-mortal-los-trabajos-de-furfarero/> SEPTEMBER 3-9 INGENIERO WHITE.COM Deadly Fentanyl : ANMAT will conduct real-time monitoring of narcotics and psychotropic substances. Through a provision in the Official Gazette, the agency incorporated a series of substances into the National Traceability System

<https://www.ingenierowhite.com/2025/09/03/fentanilo-mortal-la-anmat-hara-un-monitoreo-en-tiempo-real-sobre-estupefacientes-y-psicotropicos/> 3-09 LA NACION Contaminated Fentanyl : ANMAT's traceability system is updated after serious flaws detected in controls. This includes reorganizing the list of drugs that the agency must monitor from importation to dispensing. <https://www.lanacion.com.ar/sociedad/fentanilo-contaminado-actualizan-el-sistema-de-trazabilidad-de-la-anmat-tras-las-graves-fallas-nid03092025/>

6-09 INFOBAE KLIPPAN. One by one, the cases of "diversion" of fentanyl from medical use to the illegal market and the connection with García Furfaro 's laboratory

In the last three years, more than a dozen cases have been registered, including that of cocaine adulterated with carfentanil . Among those arrested are nurses and medical representatives.

<https://www.infobae.com/politica/2025/09/06/uno-por-uno-los-casos-de-desvio-de-fentanilo-de-uso-medico-al-mercado-ilegal-y-la-conexion-con-el-laboratorio-de-garcia-furfaro/>

12- ROSARIO 3 Contaminated Fentanyl : The former head of INAME admitted control failures and pointed the finger at the HLB Pharma laboratory

<https://www.rosario3.com/informaciongeneral/Fentanilo-contaminado-la-ex-titular-del-Iname-admitio-fallas-de-control-y-apunto-contra-el-laboratorio-HLB-Pharma-20250912-0029.html>

12 Deadly Fentanyl : One of the raided officials stated that the laboratory could not produce medications. Analyze the technical semantics that describe facts that are limited to describing and suggesting, an act proper to an auditor and not to an inspector/official acting with the powers of a health police officer.

http://www.identidadcorrentina.com.ar/noticia/25161_fentanilo-mortal-una-de-las-funcionarias-allanadas-declar-que-el-laboratorio-no-poda-producir-medicamentos.htm

12/09 CONTAMINATED FENTANYL: THE CASE CONTINUES WITH A SHOCKING REVELATION

<https://341media.com.ar/index.php?pagina=detalle&idp=9958>

16- ERREPAR Fentanyl and product liability. Javier A. Cresseri SEARCH!!!!

20/09 INFOBAE Deadly Fentanyl : Two officials met with the lab owner four months before the scandal. These officials are the head of ANMAT (National Administration of Drugs, Food and Medical Technology) and the former head of INAME (National Institute of Medicines). The meeting, held on January 14, addressed the closure of Ariel García Furfaro 's lab . This closure eventually occurred, but the deadly drug had already been manufactured.

<https://www.infobae.com/politica/2025/09/20/fentanilo-mortal-dos-funcionarias-se-reunieron-con-el-dueno-del-laboratorio-4-meses-antes-del-escandalo/>

30/09 Chemists in Buenos Aires province are calling for stricter controls on pharmacies' registration due to fentanyl contamination. The president of the Buenos Aires Chemistry Council, Carlos Colangelo , warned about the lack of oversight in the registration process.

<https://www.eleco.com.ar/provincia/quimicos-bonaerenses-piden-reforzar-los-controles-de-las-matriculas-por-el-fentanilo-contaminado>

OCTOBER

06/10 ARGENTINE TIMES Contaminated Fentanyl : Deaths Now at 124

The information comes from the prosecution of the 13 defendants.

https://www.tiempoar.com.ar/ta_article/fentanilo-contaminado-ya-son-124-las-muertes/

20/10 ENCRIPDATA. The fentanyl route. The Government allows the import of 20 kilos of fentanyl per year without analyzing the actual consumption by laboratories.

<https://encripdata.com/2025/10/20/gobierno-importar-20-kilos-fentanilo-consumo-efectivo-laboratorios/>

October 22 - Relatives of 124 victims of adulterated fentanyl in Argentina demand justice: "It's an unprecedented massacre." Those who lost a loved one to bacteria found in the drug are demanding an investigation into the entire chain of responsibility.

<https://elpais.com/argentina/2025-10-22/familiares-de-124-victimas-de-fentanilo-adulterado-en-argentina-piden-justicia-es-una-masacre-sin-precedentes.html>

27/10 PHARMABIZ

<https://www.pharmabiz.net/anmat-con-dupla-de-inhibiciones/>

28/10 DIGITAL AIR

<https://www.airedesantafe.com.ar/actualidad/anmat-ordeno-la-suspension-un-reconocido-medicamento-ser-peligroso-la-salud-n634516>

28/10 INFOBAE

The clue of the new ANMAT: how it updates controls on laboratories and makes product regulation more flexible.

<https://www.infobae.com/salud/2025/10/28/la-pista-de-la-nueva-anmat-como-actualiza-controles-a-laboratorios-y-flexibiliza-la-regulacion-de-productos/>

X VERRIER

<https://x.com/verrierm/status/1161956636552024064>

October 28 - CONTAMINATED FENTANYL: A NEW MEETING WAS HELD WITH THE PRESENCE OF THE VICTIMS' FAMILIES.

The Special Commission for Monitoring and Investigation into contaminated and/or adulterated fentanyl , chaired by National Deputy Mónica Fein of Encuentro Federal, received testimonies and proposals from the victims' families.

<https://www.hcdn.gob.ar/prensa/noticia/FENTANILO-CONTAMINADO-SE-LLEVO-A-CABO-UNA-NUEVA-REUNION-CON-LA-PRESENCIA-DE-FAMILIARES-DE-LAS-VICTIMAS/>

October 29th: The Government eliminates "Good Manufacturing Practices" inspections for imported medications. The national government has eliminated the requirement for ANMAT (National Administration of Drugs, Food and Medical Technology) technicians to travel to the country of origin of imported medications to verify their quality. This measure could reduce the price of medicines.

<https://www.perfil.com/noticias/salud/el-gobierno-elimina-inspeccion-de-buenas-practicas-de-fabricacion-en-medicamentos-importados.phtml>

29/10 The Government eliminated a requirement for importing medicines: Will prices in pharmacies go down?

- This refers to the obligation for ANMAT technicians to personally inspect laboratories in other countries where drugs are manufactured.
- The measure could expand the range of remedies on the market and allow more affordable products to enter.

https://www.clarin.com/sociedad/gobierno-elimino-requisito-importar-medicamentos-bajaran-precios-farmacias_0_LxNROeAVg3.html

IBERO-AMERICAN AUTHORITIES NETWORK
https://www.redeami.net/docs/docs/directorio_de_autoridades/Argentina.pdf The Argentine advisor to DINAVISA (Paraguay) is Carlos Chiale , former administrator of ANMAT (2015-2019). He is linked to Provision 10564/2016, which streamlined traceability without mandating a digital system for fentanyl (under Law 17.818, manual controls). Explanations: prioritizing manual narcotics due to complexity; possible industrial influence; implementation shortcomings aimed at avoiding bureaucracy. Sources: ANMAT, Dinavisa PDF payroll, Infobae .

<https://x.com/grok/status/1955639370117185714> VALUE CHAIN REPORTS August 2018

https://www.argentina.gob.ar/sites/default/files/sspmicro_cadenas_de_valor_farmacia_0.pdf

<https://cancilleria.gob.ar/es/cei/actualidad/nuevos-informes-sobre-el-mercado-farmaceutico-africano>

<https://www.caeme.org.ar/sociedad-y-medicamentos/> ANMAT WEBSITE SSCE LISTS NATIONAL REGISTER OF CHEMICAL

PRECURSORS. The Interjurisdictional Committee of the Register of Chemical Precursors is hereby created.

<https://www.argentina.gob.ar/normativa/nacional/decreto-2094-2008-148030/texto>
<https://www.argentina.gob.ar/anmat/regulados/controlespecial/listados>
<https://www.argentina.gob.ar/anmat/regulados/controlespecial/normativa>
https://www.anmat.gob.ar/webanmat/Legislacion/Medicamentos/Disposicion_38-1990.pdf
<https://trazabilidad.pami.org.ar/trazamed/consultaCatalogoByGTIN.tz> <https://curecompass.com.ar/la-trazabilidad-de-medicamentos/>
<https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2023.00686>
https://www.anmat.gob.ar/alertas_medicamentos.asp https://fda.zoomgov.com/rec/play/FTZCPsHYxkyLiuv3P-sp1Vx-lMDYDPmee7sEY2aPT_9aOOLkAguNB5ODBKjnya3j1ZKedsNnf1n1vsG.ne-yaz3d5QYxnkuEt?eagerLoadZvaPages=&accessLevel=meeting&canPlayFromShare=true&from=share_recording_detail&continueMode=true&componentName=recplay&originRequestUrl=https%3A%2F%2Ffda.zoomgov.com%2Frec%2Fshare%2F_CriELWovFPwqNJmZWxgXPYlxfRS4qOc7vo7jMprNQYoX6woCaZO76n_rvyNr.salgGs2VgdR5OHP1
<https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/what-we-investigate/criminal-case-activity> <https://www.justice.gov/usao-sdtx/pr/texas-medical-center-institutions-agree-pay-15m-record-settlement-involving-concurrent> <https://www.justice.gov/archives/opa/pr/opioid-manufacturer-endo-health-solutions-inc-ordered-pay-1536b-criminal-fines-and> <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/what-we-investigate/featured-programs> <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/what-we-investigate/laws-enforced-fda> <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/what-we-investigate/investigative-priorities> <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-basics>