

Public and private capacities for local manufacturing of pharmaceuticals: Argentina

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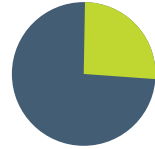
Ministerio de Salud
Argentina

DIAGNOSIS OF THE PRODUCTIVE HEALTH SECTOR

- Pharmaceuticals
- Chemical
- Biotechnology
- Nanotechnology
- Clinical trials



+250 pharmaceutical laboratories
+10 pharmachemical companies
+200 biotech companies
+40 nanotech companies



Health spending accounts for **+9.5% of GDP**



+18.5% of public R&D expenditure



+USD 1 billion of exports



+50,000 formal jobs
+3,000 R&D jobs



+1,000 active clinical trials in the country
+4,500 researchers
+130 pharmachemical drugs

Capacities and opportunities in the pharmaceutical industry

» The health industry has significant capabilities and potential for expansion

1

Capacities

- **230 pharmaceutical plants** throughout the country. 182 of them are nationally owned companies.
- More than **40 public laboratories** producing medicines and medical products.
- 13 of the top 15 **exporting** companies are **of national origin**.
- More than **900** registered **research centres** and **250 ethics committees** for clinical trials.
- 30 Research & Development Centres and 46 Regional Centres for industrial technology.
- **Universities:** 113 universities and 19 university institutes.

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Opportunities

- Argentina is among the top 20 countries in the world's largest biotech companies.
- **Many projects** generated by the national S&T system **end up being developed and producing goods or services abroad**.
- Although the government and the private sector invest in R&D, **the rate of developments reaching the market is low**.
- In Argentina **R&D investment, reaches barely 3% of sales**, while in Europe for example, it represents between 13% and 14%.
- The country has a **shortage of** medicines, vaccines, medical supplies and equipment.

Capacities and opportunities in biological medicines

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Capacities

- **60** biopharmaceutical **companies**.
- 5 companies produce biopharmaceuticals in the country, supplying **24% of the domestic market**.
- **80%** of local production is **exported**.
- Strong **articulation** with science infrastructure and national and international technology.
- **46%** of **social welfare** purchases are biologics (95% are biotech).

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Opportunities

- Growing weight of biopharmaceuticals.
- Patents on some biologics expire in 3 o 4 years.
- Local development of biosimilars.
- National Institute of Viral Diseases tenders new **multi-purpose** vaccine production **plant**.
- **Policy of productive incentives:** Buy National Act, Knowledge Economy Act, Promotion of Modern Biotechnology Act, Promotion of Nanobiotechnology Act, Tax Incentives, Subsidised Credits, etc.

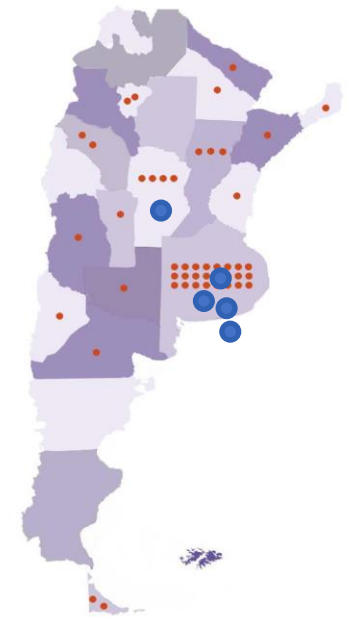
Public Production of Medicines. Vaccine production capacities

- National Institute for the Production of Biologicals (INPB-ANLIS): anti-rabies viral, BCG, BCG Immunotherapeutic, Double Bacterial.
- National Institute of Human Viral Diseases (INEVH-ANLIS): Candid#1
- Laboratory of Haemoderivatives (LH): development of recombinant biosimilar products, sterility packaging.
- Armed Forces Joint Pharmaceutical Laboratory (LFC): Double Bacterial sterility packaging.
- Instituto Biológico Dr. Tomás Perón (IBTP): anti-rabies viral, BCG, BCG Immunotherapeutics, Double Bacterial.

Public Production of Medicines. Vaccine production capacities

- Public production laboratories have the capacity to produce strategic vaccines and develop new projects.
- They handle various technologies for cell culture, which can be applied to vaccine production. In some cases they are currently part of the vaccine production process and in other cases they are under development.

Laboratory	Type of crops
National Institute for Biologicals Production (INPB-ANLIS)	Bacteria and Animal Cells (Vero)
National Institute of Human Viral Diseases (INEVH-ANLIS)	Animal Cells (FRhL-2)
Blood Derivatives Laboratory (LH)	Animal Cells (CHO)
Armed Forces Joint Pharmaceutical Laboratory (LFC):	N/A Capacity in packaging
Dr. Tomás Perón Biological Institute (IBTP)	Bacteria and Animal Cells (BHK21 / Vero)



Map of Argentina showing the location of public production laboratories. Blue indicates laboratories with vaccine production capacities.

Public Production of Medicines. Vaccine production capacities

➤ Multipurpose vaccine plant project

- Multipurpose and flexible plant for different types of vaccines located at the premises of the National Institute of Human Viral Diseases (INEVH-ANLIS) in the province of Buenos Aires.
- Investment of USD 5 million.
- New 720 m² plant and 350 m² warehouse. New laboratories are incorporated and part of others are refunctionalised.
- Capacity fill and finish. 5000 vials per hour.
- Strengthening of 4 strategic areas: Argentine Haemorrhagic Fever, Dengue, Yellow Fever and other Arboviruses, Hantavirus and production of immunobiologicals of strategic importance.
- GMP laboratory facility for the provision of Active Pharmaceutical Ingredient (API) production services and vaccine batches for clinical trials.
- Incorporating an R&D&I area for the development of new vaccine production technologies.
- Yellow Fever. Technology transfer with FIOCRUZ in the framework of the Argentina-Brazil health cooperation and joint work agreement.



Public Production of Medicines. Vaccine production capacities



Strategic partner for public vaccine production: National public academic sector

Scientific-technological centres that carry out R&D in Vaccines

- **7 Public National Universities**
- **1 Private University**
- **4 National Public Institutes**
- Animal immune response to specific antigens of circulating HIV BF variants.
- Immune response, immune evasion and immunopathogenic mechanisms. Pathogen-host relationship in Brucella spp. infections. R&D of prophylactic and therapeutic vaccines (Chagas, leishmaniasis and yellow fever).
- Protein-based R&D against COVID-19. Heterologous vaccination as a preventive strategy to overcome pertussis. ARGENVAC development.
- ARVAC vaccine against COVID19: pre-clinical and start of Phase I. Search for new adjuvants for oral vaccines.
- Development of a therapeutic vaccine against lung cancer, induction to respond immunologically to tumour cells.
- Animal anti-rabies;
- Experimental oral vaccine against Chagas disease. Search for adjuvant strategies. Nanostructured system (coagel) as a platform, liquid crystal bilamellar system (CIBICI, CONICET).
- Development of polyclonal IgY antibodies, recombinant proteins and SARS-CoV-2 neutralising nanoantibodies.
- Third generation human rabies vaccine,
- Development of veterinary, subsequent human rabies vaccine in Vero cells.
- Biological drug development, recombinant protein production, pilot plant research for scale-up of CHO cell culture.