



# ANMAT

Administración Nacional de Medicamentos,  
Alimentos y Tecnología Médica

---

## **NATIONAL PROGRAM FOR MARKET CONTROL OF MEDICINES AND MEDICAL DEVICES**

The National Program for Market Control of Medicines and Medical Devices implemented by A.N.M.A.T. is carried out by specialized professionals who inspect establishments countrywide in order to combat the illegal marketing of medicines and medical products.

The Program was created in 1997, under the name "National Program of Search of Illegal Drug Products", with the purpose of fighting a problem that gained momentum at that time: the upcoming of gangs that manufactured drugs intended for treating various diseases in unlicensed premises, even in sheds.

Ever since the program was implemented, the sale of counterfeit drugs has decreased significantly. This Program was rolled out in the framework of a technical and scientific agreement signed by the National Health Authority, the pharmaceutical industry and associations of professionals. Thereby, A.N.M.A.T. was empowered to conduct inspections in premises nationwide in order to counteract the trade of counterfeit drugs.

Likewise, the Justice System took its part in that initiative by investigating the offenses. Under Order 54/1997 of the Attorney General, a Prosecutors Committee was established. Therefore, when an offense is proved, proceedings are referred to the relevant Federal Courts that take the relevant actions and punish offenders.

In the light of the momentum gained by a worldwide trend that fosters joint action for preventing and fighting the counterfeit of medicines and medical devices or products; and considering the experience acquired through the National Program of Search of Illegal Drug Products, the action scope of the latter was enhanced by means of Regulation 2124/2011 by which the National Program for Market Control of Medicines and Medical Products was created, with a view to encompassing the monitoring for legitimacy of medical devices available in the market.

### **Work methodology**

- Sight and/or organoleptic inspection of drug products at the various steps of the marketing chain.
- Investigation of commercial documents and/or possession of drug products.
- Sampling of drug products.
- Quality control of products seized at the various steps of the marketing chain.

### **Action scope**

The action scope of the Program is nationwide and applies to all the establishments where medicines and medical devices are manufactured, traded and stored. In the framework of the Argentine Republic federal system, monitoring tasks are performed in various provinces. For this purpose, the relevant jurisdictional health authorities are previously notified and grant their authorization.

### **Classification of illegal medicines**

1. Counterfeit drug products.
2. Adulterated drug products.
3. Drug products stolen during marketing stage.
4. Smuggled drug products.
5. Unregistered drug products.
6. Marketed samples of drug products or medical gifts.
7. Expired drug products.

When a drug product is detected as an alleged illegal medicine during an inspection, a representative sample of the product batch/es is taken and later analyzed for legitimacy at the Instituto Nacional de Medicamentos (National Institute of Drugs - INAME) under A.N.M.A.T. In case other units remain at the establishment inspected, such units are preventively prohibited for use and sale until their legitimacy is verified.

### **Main actions taken when illegal drug products are detected**

1. A countrywide prohibition on use and marketing of the batch involved is implemented.
2. A report is submitted to the Prosecutors Committee created under Order 54/1997 of the Attorney General.
3. A follow-up of the existing units in the market, based on the suppliers involved in their distribution is performed.

4. A report to the jurisdictional/national/regional/WHO health authorities is issued.

### **Tips for consumers**

- Acquire drug products at duly licensed pharmacies.
- Do not acquire drug products on the street or internet.
- Verify the quality of packaging and distrust drug products packaging with crossing outs, amendments or signs of statements, logotypes or labels having been deleted.
- Do not acquire products of which security devices (e.g. wax seals, security seals) were broken.
- In case of doubt about the legitimacy of a drug product, contact "A.N.M.A.T. Responde" Program at 0800-333-1234 toll free number or the National Program for Market Control of Medicines and Medical Devices at (54 11) 4340-0800, ext. 2562.
- If you are doubtful about the legitimacy of a product and want to inform us, you can fill in the on-line form **"Notification of alleged illegal medicine or medical device" on the "Drug Products"** link on A.N.M.A.T. website or otherwise in person at 2161 Caseros Av (reception desk), from 9.00 to 13.00.