

# Experience in traceability of essential drugs in the public sector

## ABSTRACT

*The Remediar Program begins in Argentina in 2002 in the framework of a crisis which our country experienced, as a national sanitary policy which intended to guarantee drug access to the most vulnerable population. The results obtained regarding drug access, supported by a new logistic system for the public sector for quality and reach, since 2009 it was possible for Remediar to become a logistics' operator of Programs and Directives of the National Ministry of Health which provide drugs and medical supplies.*

*ANMAT's provision related to the drug Traceability System is a great challenge for the public sector as a whole. In this article we intend to detail the work from Remediar and the adaptation of its processes to comply with the regulation in force and to extend drug traceability until it reaches the patient in the public system sector.*

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The *National Drug Policy* arises as one of the decisions that enabled to face the social and institutional crisis that took place in Argentina at the end of 2001. Its primary objective was to promote equity and to guarantee drug access to the population with exclusively public health coverage, integrating as central components the *Ley de Promoción de la Utilización de Medicamentos por nombre Genérico* [Law of Promotion of Drug Use by Generic Drug] and the free supply of essential drugs to the First Level of Care (PNA) through the Programa Remediar.

By *Mauricio Monsalvo*



Remediar was designed with the purpose of encouraging long lasting reforms in the public health system, prioritizing the strategy of Primary Healthcare (APS). After 11 years of history, it proved to be an efficient policy that guarantees Argentineans access to drugs and contributes to ensure the population the right to health from the strengthening of the resolution capacity of the provincial public systems and the financing of a social good and of high redistributed impact like drugs.

From its beginning, Remediar has reached monthly directly and uninterruptedly more than 7,000 Primary Healthcare Centers (CAPS) distributed in the whole country, with first-aid kits with a vademecum of essential drugs responding to the 80% of the consultations of first care level, guaranteeing the coverage for more than 15 million users of the public health system. Free drug supply represented a financing modality which enabled a wider, more equitable and focalized access for the population in need. Its implementation required transparent mechanisms of negotiation between the health system and drug suppliers, Remediar became the most important program for drug purchasing and distribution of Latin America.

Remediar first-aid kits have a list of 54 essential drugs which were originally consented between the National Ministry of Health and the total of the Argentine provinces. Drugs reach the pharmacy of the CAPS directly, without stopping at provincial or municipal intermediate warehouses.

With the purpose of guaranteeing the transparency and the competence, the Program performs public tenders for the purchase of the drugs it distributes. This way, at the instance of the preparation of bidding documents a series of technical requirements are established which enable us to guarantee product quality from the

purchase selection stage to the delivery of the first-aid kits in the CAPS and to the posterior dispensation of the pharmacological treatment.

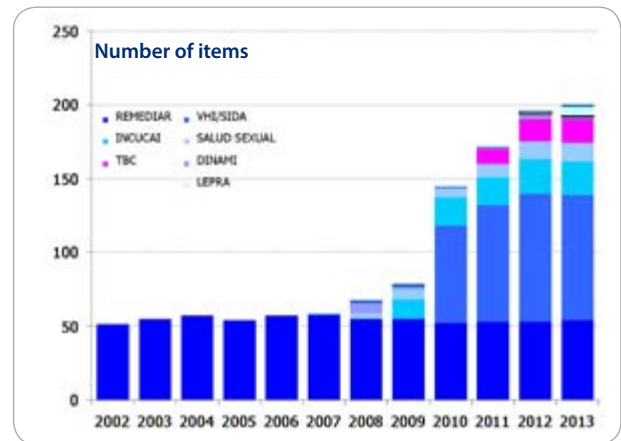
Its design contemplates the outsourcing of storage, production and distribution processes in two private logistic operators, authorized by the National Administration of Drugs, Foods and Medical Technology of Argentina (ANMAT), who become the executors of the public tender.

The drugs have their own package, requested to the suppliers in the bidding document. This way, the packages present secondary packaging colors chosen according to the anatomical groups over which they act and from the Anatomic Therapeutic Chemical Classification (ATC). Twelve different colors are used which facilitate the drug organization in the pharmacy at the CAPS. The quantity of primary units per package is defined for each product in accordance with the official therapeutic guides or schedules, in order to adjust the size of the packages to the recommended treatments, thus promoting the rational drug use and avoiding the unnecessary expenditure of financial resources. On the other hand, secondary packages have a data carrier of public domain DATAMATRIX ECC200 (data codification 2D), which indicates the GTIN, lot, expiration date, Remediar product code and, when applicable, the unambiguous serial. Moreover, the expiration date is expressed in format "MM-YY" for an easier identification.

From 2009 Remediar became the Logistic Operator of the Programs and Directives of the National Ministry of Health which provides drugs and medical supplies due to the experience and good results achieved in relation

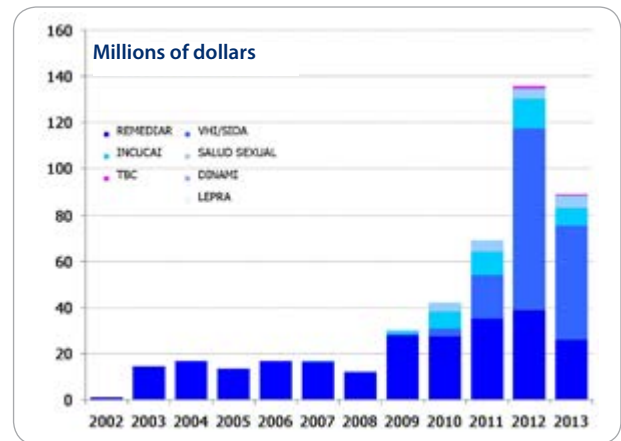
to the logistic distribution. Figures 1 and 2, shown below, demonstrate the volume growth of the distribution incorporated by the Program in the last years.

**Figure 1: Progress of units distributed by Remediar according to the Program.**



Source: Created by the author

**Figure 2: Progress of Remediar transfers. In millions of dollars..**



Source: Created by the author



Traceability is a tool that enables the registration, the knowledge and the verification of the origin and the final destination of the drugs, and their movements and transfers along the whole distribution chain. Therefore, a drug traceability system enables to guarantee their control and contributes to eradicate the circulation of those which are illegitimate. From the beginning, Remediar understood the importance of having a drug traceability system which purchases and distributes, from its own information system which enables a follow up of the product at lot level from its reception until it reaches the CAPS.

ANMAT's provision 3683/2011 related to the drug Traceability System which intends to professionalize the processes involved in the drug supply chain cycle, implies an important challenge for the actors of the public health sub-sector. Facing this challenge the National Ministry of Health in general and RemediAR in particular, are working to adapt their processes, to fully comply with the regulation and to extend it to the patient's delivery in the area of the public health system.

In relation to the improvement of the processes in the central level, the Program is executing a plan of technology incorporation in the drugs' warehouses and a quality certification plan (ISO 9001) for critical processes. On the other hand, it is in its implementation phase the exchange of electronic information with suppliers for the improvement of drug reception processes.

Moreover, with the purpose of consolidating a federal drug supply network in the public area, RemediAR started the survey of approximately 60, provincial regional and municipal warehouses. The objective of this survey is to identify the breeches in the current state of affairs in relation to the compliance requirements of the Good Distribution Practices, Storage and Transport established by ANMAT and to finance the necessary investments in furniture and basic equipment. From data collectors to racks, including signs, refrigerators, generator units and pallet transporting equipment are included in the investments. These investments are complemented with a wide training program for administrators in subjects such as traceability, good practices, pharmaceutical services and purchase planning. From 2014, hospital pharmacies will be included also in the investment plans, due to the strategic role they occupy in the distribution chain of high cost drugs and basically of hospital use.

In order to move forward in the digitalization of the dispensation in healthcare centers to guarantee traceability until it reaches the patient, it implies the performance of a series of previous actions. Healthcare services in Argentina are decentralized (in provinces and/or municipalities according to the case), and the majority already have their own computer systems. The challenge is basically not to duplicate efforts and to guarantee the flow of information from the sanitary units to the central level.

RemediAR has considered incorporating to the digital pattern of transmitting information more than 1,000 healthcare centers in the next two years. Therefore, it has been performing surveys in the field to have a proper diagnosis in relation to the main characteristics which the healthcare centers present mainly in terms of availability of physical space for the delivery of drugs, furniture, and computer equipment. The National Ministry of Health's investment in regard to furniture (mainly furniture for the drugs storage and work tables) and computer equipment (computers and data optical scanners) with information systems which store data of dispensed drugs and patients, will enable to guarantee the compliance of the traceability circuit and to have improved and more information available for decision making.

#### ABOUT THE AUTHOR

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*He graduated in Political Science at the University of Morón. He has a Master's degree in Social Research Methodology of the Università di Bologna/National University of Tres de Febrero (without a thesis) and a Master's degree in Epidemiology Public Health at the Oswaldo Cruz Foundation (Fiocruz/ANLIS), with approved thesis.*

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