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MENU

 [RSS \(http://portal.anvisa.gov.br/noticias/-/asset_publisher/FXrpx9qY7FbU/rss?p_p_cacheability=cacheLevelFull\)](http://portal.anvisa.gov.br/noticias/-/asset_publisher/FXrpx9qY7FbU/rss?p_p_cacheability=cacheLevelFull)

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Agency starts test 1800 product samples

Program will test collected drugs on the market. In the first round were 20 lots analyzed.

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The first analyzes of the National Programme for Drug Quality Check (Proveme) gave satisfactory results for all evaluated drugs. There were seven different active ingredients, with a total of 20 samples in the first month of the program. This is only the first test result with collected products on the market. The program, which was taken over by the agency last August, provides for the analysis of 1,800 samples by 2018.

The Proveme is the collection of medicines that are available on the shelves of pharmacies, pharmaceutical companies, distributors and health departments and takes the products for analysis in public laboratories scattered throughout Brazil.

Altogether there are 13 laboratories Health Centers (Lacens) part of the action, plus the National Institute of Quality Control in Health (INCQS-Fiocruz).

Results of the first round of analysis of Proveme:

- 7 drugs
- 16 different manufacturers
- 20 lots
- 121 reviews

All analyzes gave satisfactory results.

What medications were analyzed?

In this first round the following drugs were analyzed:

- Acyclovir - two lots - antiviral used primarily in the treatment of herpes
- Amoxicillin - a lot - antibiotic
- Cimetidine - three batches - treatment of gastric ulcer
- Metoclopramide Hydrochloride - a lot - treatment of nausea and vomiting of surgical origin
- Lamivudine - five lots - Antiretroviral treatment for AIDS
- Methyldopa - a lot - used to treat hypertension (high blood pressure)
- Paracetamol - six lots - one of the most widely used analgesic and antipyretic in the country.

Average 6 analyzes medicine

Analyses made in the medicaments may vary according to the pharmaceutical form and the product characteristics. In the first round have been made, an average of 6 tests per sample. Since the most common are: the active ingredient dosage analysis, weight variation, dose uniformity, appearance analysis, labeling analysis and dissolution testing.

How is the selection and analysis of samples

The selection of drugs to be evaluated taking into account those with the highest number of notifications for technical complaints and quality deviations, the provided by the program Here Has Popular Pharmacy (<http://portalsaude.saude.gov.br/index.php/o-ministerio/principal/secretarias/sctie/farmacia-popular>), the most consumed by the Brazilian population, and those present in other Ministry of Health programs.

The collection of samples for analysis (testing) is a decentralized action, the responsibility of state and municipal coordination of health surveillance and depends on the analytical capacity of each laboratory.

Because it is tax analysis, the samples collected are divided into three equal parts, in triplicate: test sample calls, control sample and witness sample. Each envelope should contain the minimum number of samples to perform the necessary tests, such as 100 tablets in each of the parts (shells). Each sample must correspond to a single lot number and preferably be collected at least six months before the date of expiry of its validity.

What is Proverme

The Proverme is a post market share, namely that analyzes the drugs after they are already available to consumers.

An International Technical Cooperation agreement between Anvisa and the United Nations Development Programme (UNDP), last July 20, allowed the start of execution of the analysis. Under the agreement, lasting 18 months, will be analyzed 1,800 samples of drugs.

The partnership between Anvisa and UNDP for the implementation of Proverme also involves the Health Departments, 13 Central Laboratories of Public Health (Lacen), the National Institute for Quality Control in Health (INCQS-Fiocruz) and state and local coordinations Health surveillance (Visa). The coordination of Visa perform the collection of drug samples.

The program has existed since 2001 and came to analyze more than 3,000 medications. Current data mark the beginning of the resumption of Proverme.

In the last three years have not been performed analyzes in the context of a structured national program, drug analyzes were at the expense of state programs monitoring medicines and in several investigations and inspections. The result of this analysis also determines the adoption of health measures, such as marketing or suspension manufacturing, among others. Such actions may be identified through the link:

<http://portal.anvisa.gov.br/produtos-irregulares#/> (<http://portal.anvisa.gov.br/produtos-irregulares#/>)

open data

Enter here (</documents/219201/2782895/Relat%C3%B3rio+Proverme/fb5b5610-0b79-4f66-bc38-27d93e7fa55b>) the file with the data open to researchers and interested in Proverme results.

Check out (</documents/219201/2782895/Medicamentos+testados+na+primeira+etapa+do+Proverme/683f136e-7a68-4891-9667-3f8e875b947e>) what were the lots and medications tested in the first round.

analysis of drugs (<http://portal.anvisa.gov.br/noticias?>

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