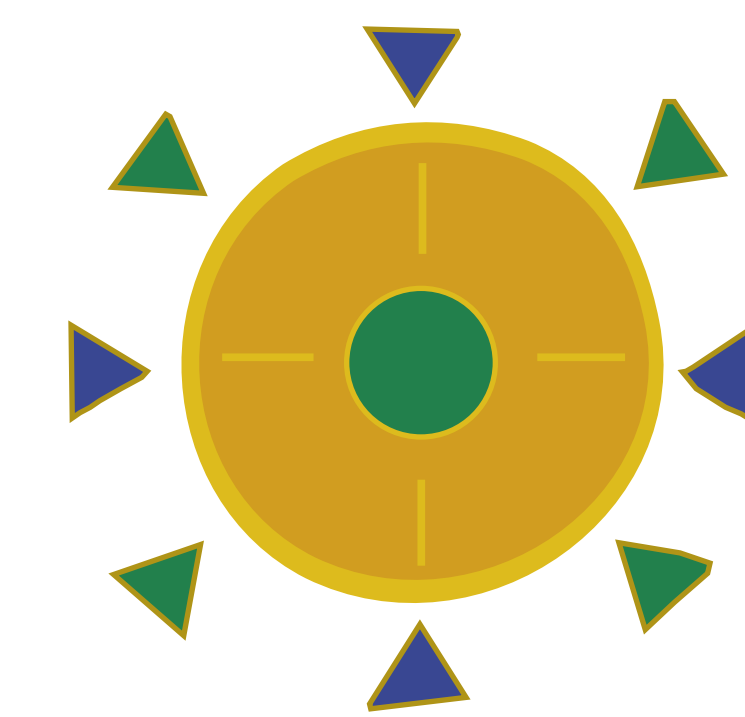


SEAM Tanzania



Quality Assurance: Inspection and Product Testing-Screening Program Review

M. Ndomondo-Sigonda,¹ O. Kowero,¹ Z. Msuya,¹ P. Risha,² M. Clark,² and T. Layloff²

¹Tanzania Food and Drugs Authority ²Management Sciences for Health

Background

Based on studies done in 10 countries, the World Health Organization has reported that up to 20% of drugs failed quality control tests. These substandard, or even fake, pharmaceutical products pose threats to the health of the general public through ineffective treatment. In addition, substandard and fake pharmaceutical products waste scarce resources. It is, therefore, important that the pharmaceutical market is effectively regulated to ensure that products used by consumers meet legal standards.

To help address these drug product quality concerns in Tanzania, the Tanzania Ministry of Health and the Tanzania Food and Drugs Authority (TFDA), with SEAM support, are developing a three-tiered product quality assurance testing and inspection program. The SEAM Program is supporting the implementation of the first two tiers for a limited number of surveillance drugs, including selected antimalarial, antibiotic, and antiretroviral (ARV) drugs. For increased impact and information management, the screening program has been coupled with a structured inspection program.

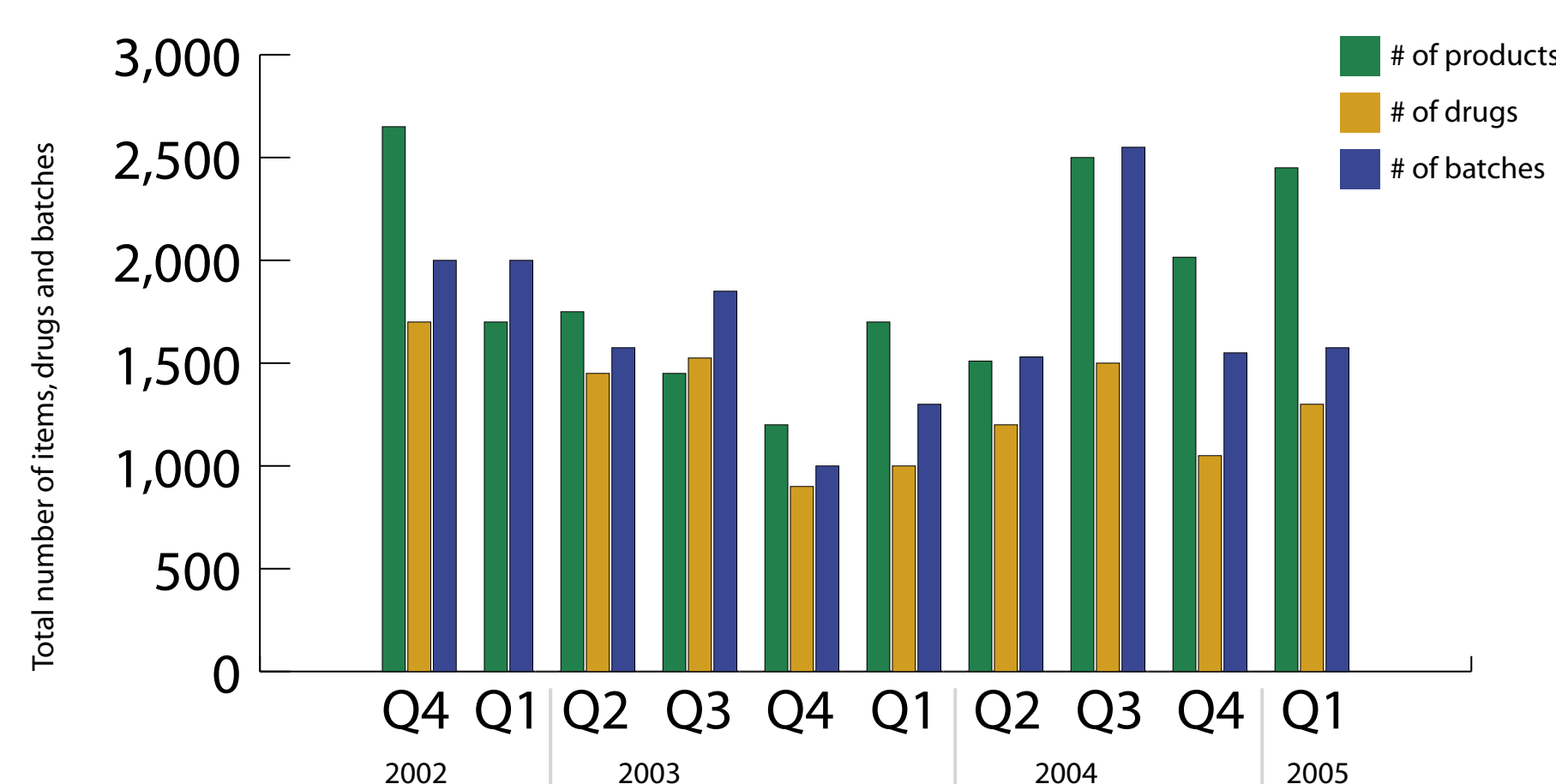


Figure 1. The graph shows the number of pharmaceuticals inspected at ports-of-entry, per quarter, from October 2002 to April 2005.

Implementation

It is estimated that over 70% of the legitimate pharmaceutical products used in Tanzania enter through the ports-of-entry (POEs) of Dar es Salaam International Airport and Namanga, or are purchased by the Medical Stores Department (MSD) for distribution through government distribution channels. In order to protect this large market share, the TFDA initiated a quality assurance program with inspection of imported drugs at POEs, postmarketing surveillance (PMS), and Minilab screening of targeted drugs sampled from both POE and PMS. At the POE, the inspector conducts documentation and labeling examination on all consignments, performs physical examination on all batches of medicines, and takes samples of targeted surveillance medicines for Minilab screening. Any noncompliant consignments are not released from POEs. The TFDA coordinates and shares responsibility with MSD to monitor drug product quality coming into those channels.

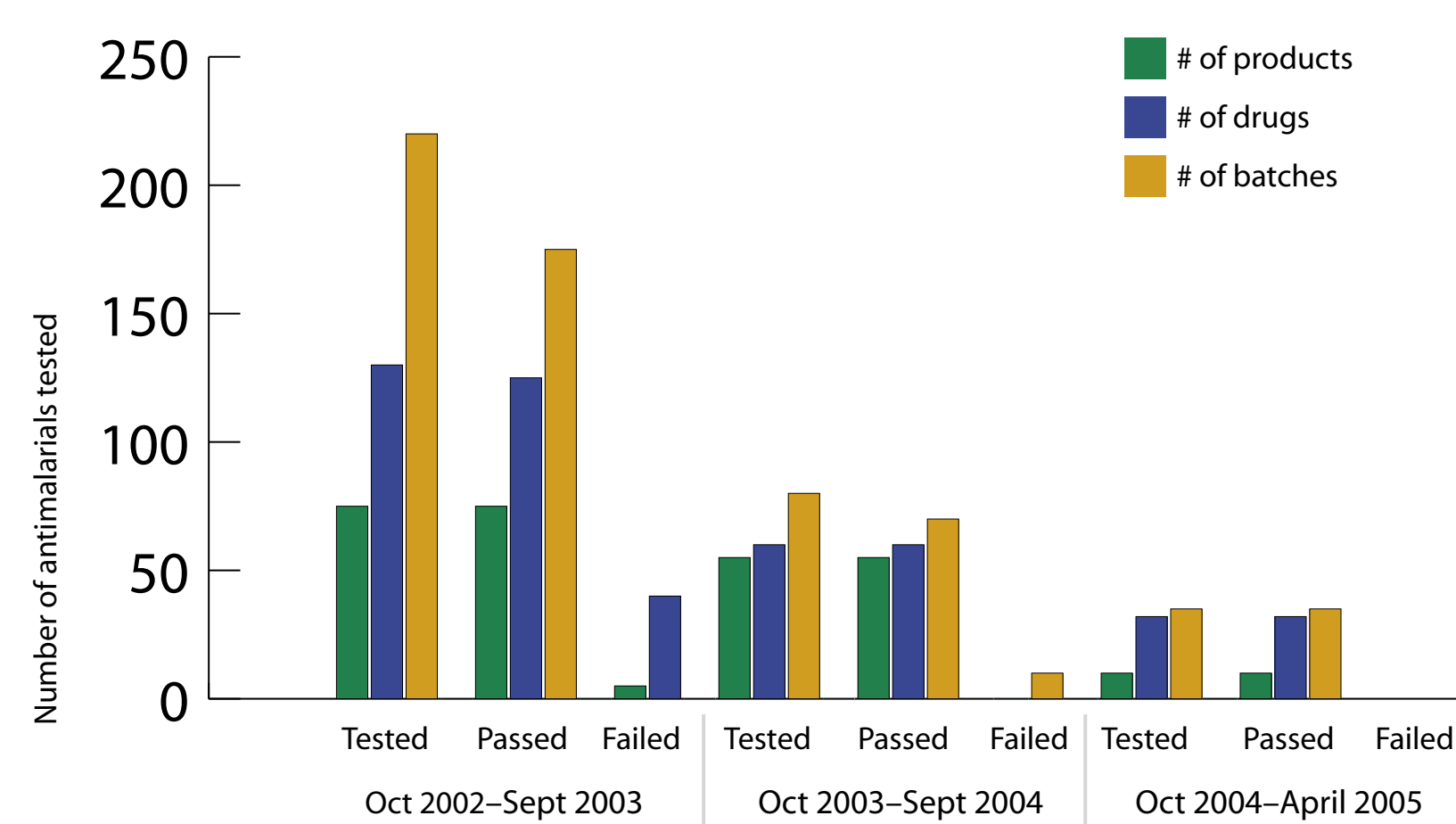


Figure 3. The graph shows the results of antimalarial drug screening/testing from the program launch in October 2002 to April 2005.

During PMS, the inspectors perform premises and products inspection to help ensure conformance to established quality standards. Nonconforming products are confiscated or quarantined, depending on the nature of violation. The quarantined products are sampled and sent to the TFDA quality control laboratory for further analysis. In addition, the inspectors take samples of the targeted drugs for Minilab screening.

Observations

Since the launch of the program in October 2002, the number of consignments inspected at POEs has increased significantly. A total of 7,800 consignments, about 3,200 consignments per year, containing 28,185 batches of pharmaceutical products, have been inspected since the program launch (Fig. 1). The efficiency of the inspection processes has been aided by uploading forms for product and premises registration data, as well as inspection forms, to personal digital assistants (PDAs); upon completion, the inspection forms may be automatically downloaded into an Access database.

The number of drug dispensing outlets inspected also has increased significantly; the number of facilities inspected one year post-launch increased about fourfold (Fig. 2), and the trend has been maintained throughout the program implementation.

Testing of drugs at the TFDA laboratory has been complemented by Minilab screening. A total of 1,257 batches of the targeted drugs have been screened/tested. Of these, 1,211 passed and 46 (3.7%) failed; the majority of the failing drugs were sulfadoxine/pyrimethamine tablets that failed the dissolution test. In addition, the number of target drugs, which initially included only antimalarial medicines has been expanded to include selected antibiotics and ARV drugs. The number of batches of each drug category tested is shown in Figures 3–5.

Discussion

The PDA-assisted inspection processes have improved the speed, accuracy, and efficiency of the inspections. These efficiencies in inspectional data acquisition have allowed a large number of inspections to be conducted by relatively few inspectors. In addition, the Minilab product screening in the field requires an average of 1.5 hours per sample; screening of approximately 1,200 samples over the 2.5-year period since program launch required a total of only about one person-year of activity. These efficiencies and data handling systems have enabled a significant presence of the TFDA in the marketplace, and this in turn poses a significant deterrent to the marketing of substandard and counterfeit products by unscrupulous and/or incompetent product manufacturers and distributors. The inspection processes have resulted in numerous product confiscations and importation refusals, in addition to premises closures and standards improvements. In addition, the Minilab screening tests have identified five fake products, three quinine and two erythromycin samples, which were removed from the market.

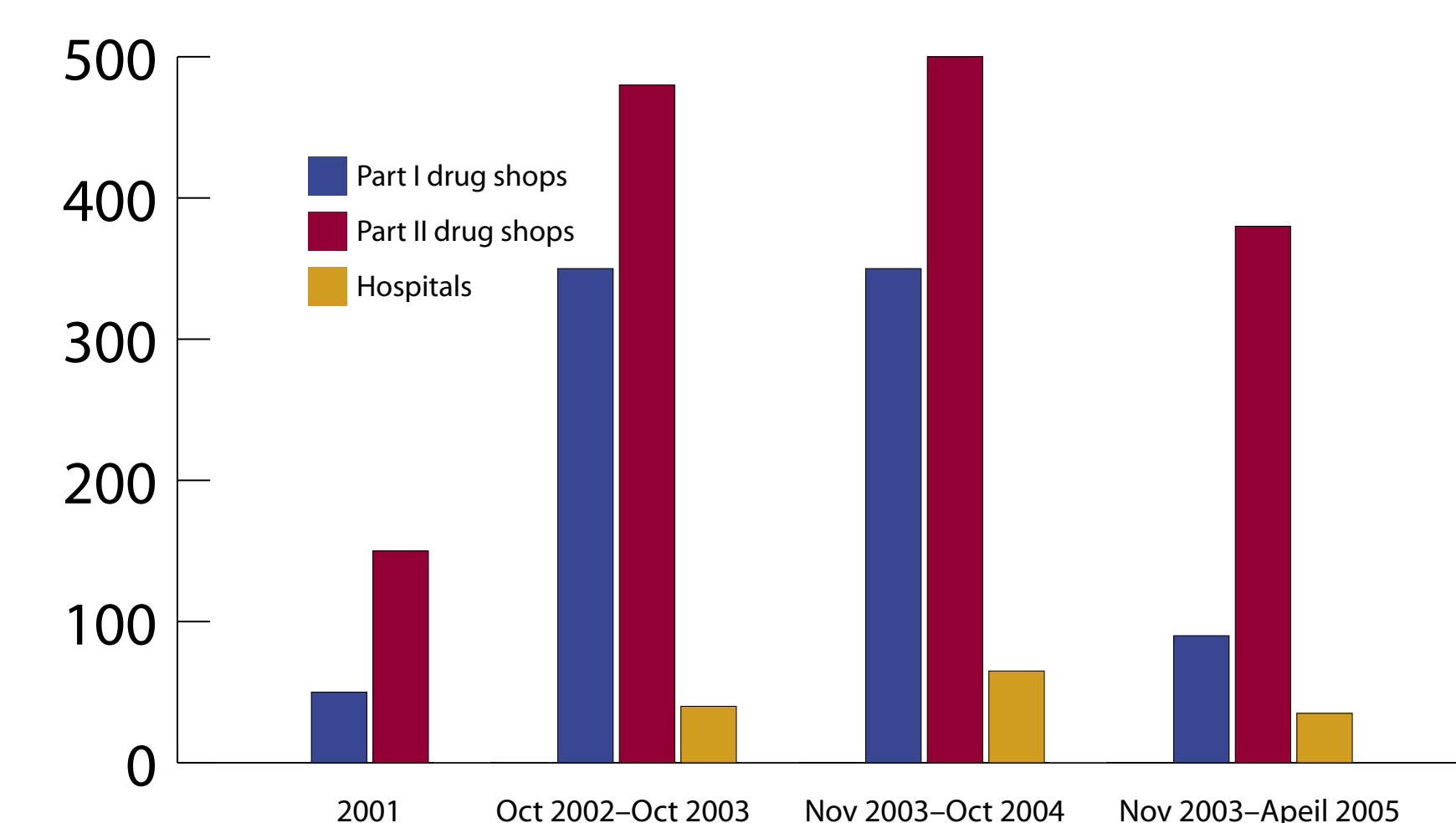


Figure 2. The graph shows the number and type of drug dispensing outlets inspected annually since the quality assurance program launch.

Conclusions

This entire program is conducted with a relatively modest level of TFDA resources yet poses a significant deterrent effect. The product screening observations also provide evidence that the upstream compliance activities of registration, record inspection, and physical examination are functioning well and reflect the improved quality of marketed products when compared to SEAM baseline studies. This universe of activity, including registration, inspection, physical examination, product screening, and laboratory testing, provides a significant deterrent to marketing illegal products, therefore improving the marketplace and allowing legitimate, conscientious manufacturers and distributors to compete.

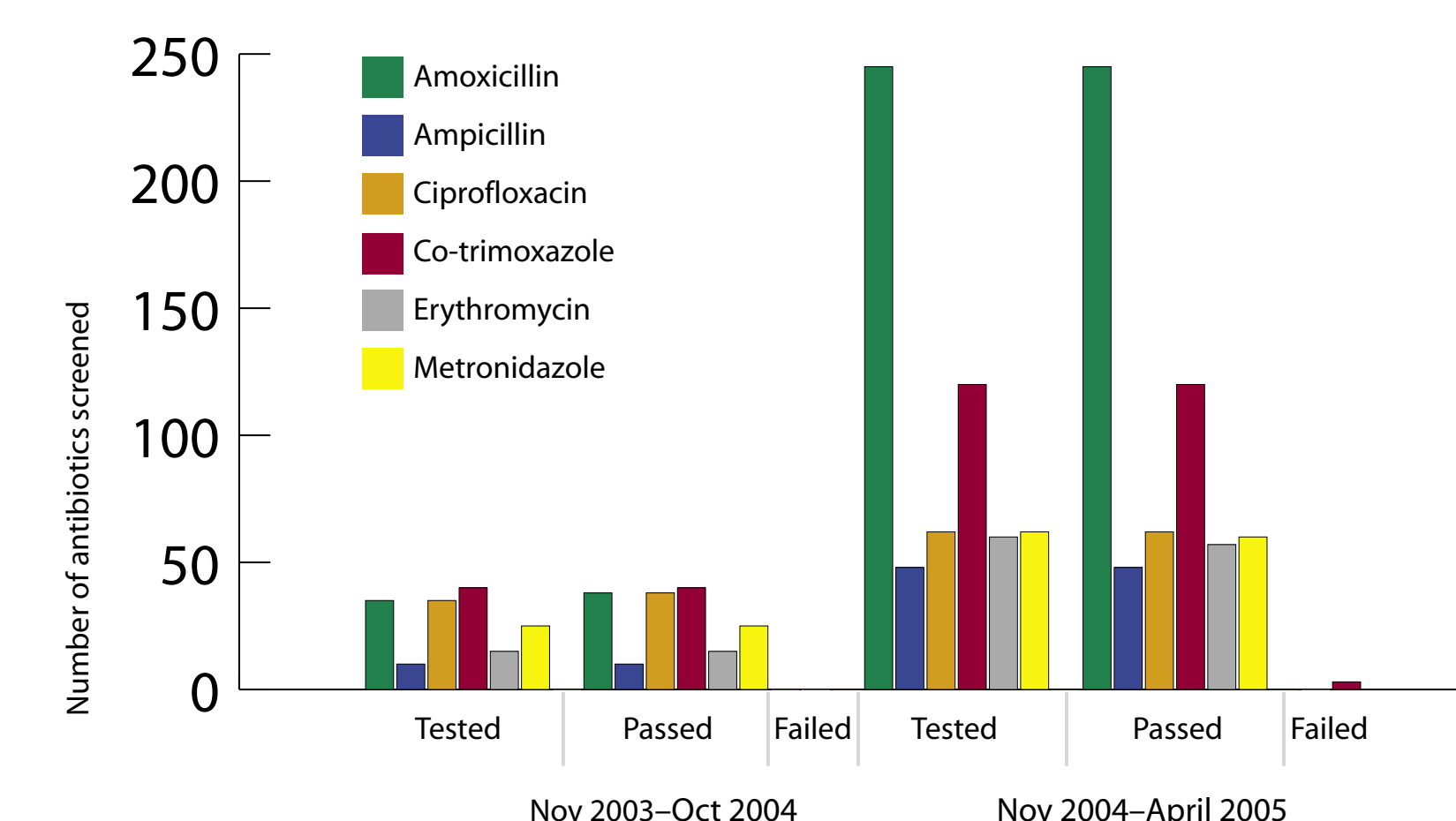


Figure 4. The graph shows the results of antibiotic screening from November 2003 to April 2005.

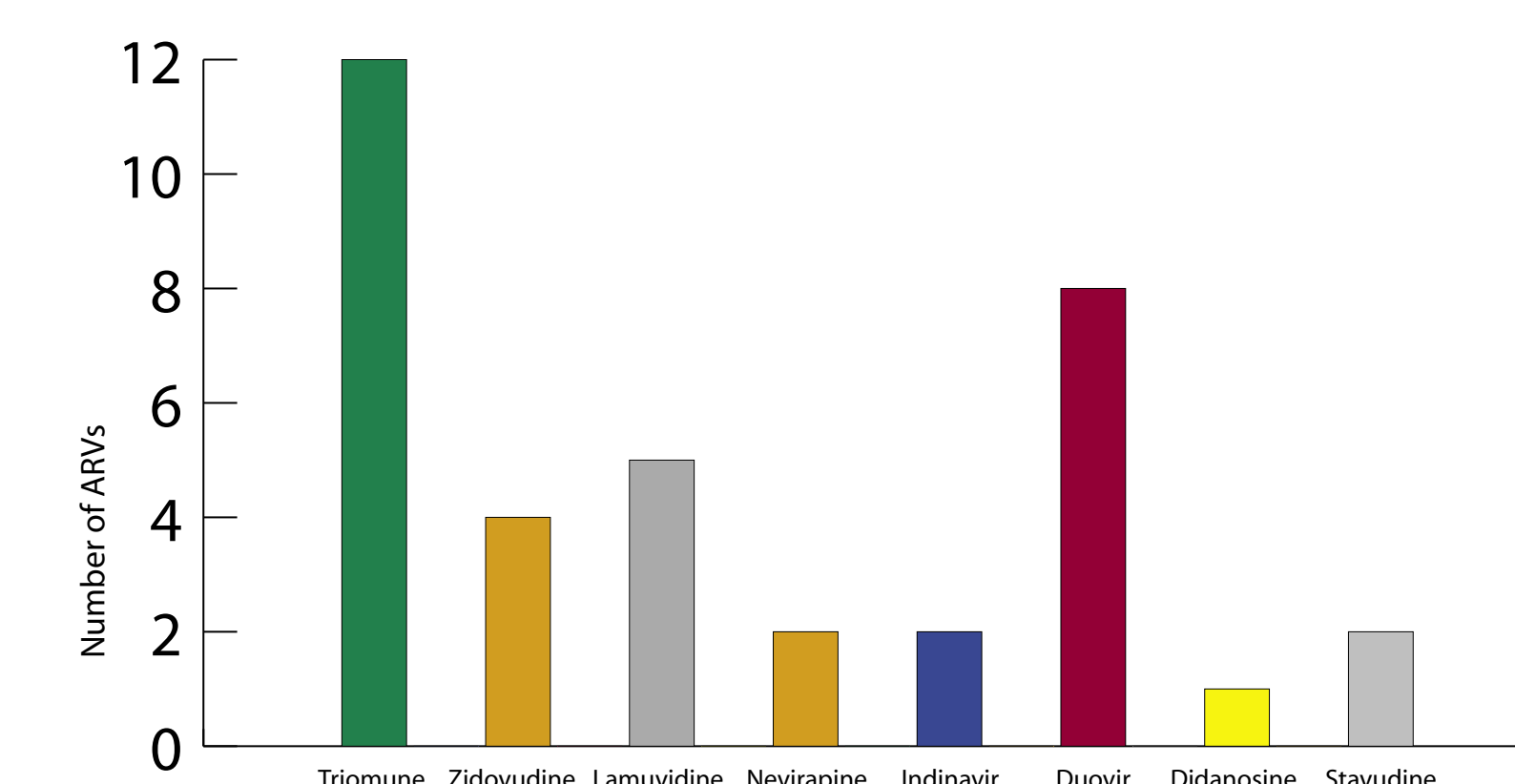


Figure 5. The graph shows the total number of ARVs, by product, screened from March 2004 to April 2005.