Control and monitoring of the use of antibiotics as a strategy against antimicrobials resistance

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contra Riesgos Sanitarios

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Context

- The burden of deaths from AMR can rise to 10 milion lives each year by 2050 (O'Neill, 2016)

- WHO 2011: Policy package to combat antimicrobial resistance

  - ✓ Irrational use of antimicrobial medicines: a major driver of antimicrobial resistance (AMR).

  - ✓ Core action: Enforce prescription-only use of antimicrobials

- WHO 2015: Global Action Plan

  - ✓ Regulation of the use of antimicrobial agents is inadequate or poorly enforced in many areas, such as <u>over-the-counter sales</u>

  - ✓ Optimize the use of antimicrobial medicines supported by <u>appropriate and enforceable regulation</u>

Actual Regulation

- Anvisa Regulation nº 20/2011

  - ✓ Establish criteria for prescribing, dispensing, control, packaging and labelling of antimicrobial drugs classified as "prescription use only" (the list includes 119 substances)

  - ✓ Pharmacies and drugstores are covered

  - ✓ prior to dispensing medications, prescriptions will be verified and retained

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National System of Management of Controlled Products (SNGPC)

- Used to control and monitor controlled products sale, including antimicrobial medicines

- Prescription data: date; patient identification; age; prescriber identification; name of prescribed substance; dose/concentration, pharmaceutical form, dosage, and quantity

- Contribute to regulatory decisions

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Expected results

- Reduce harmful self-medication

- Promote pharmacoepidemiology

- Highlight the need of professional indication for antimicrobial medicines consume

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Total antimicrobials dispensation at drugstores and pharmacies enrolled at SNGPC. May/2013 to June/2016
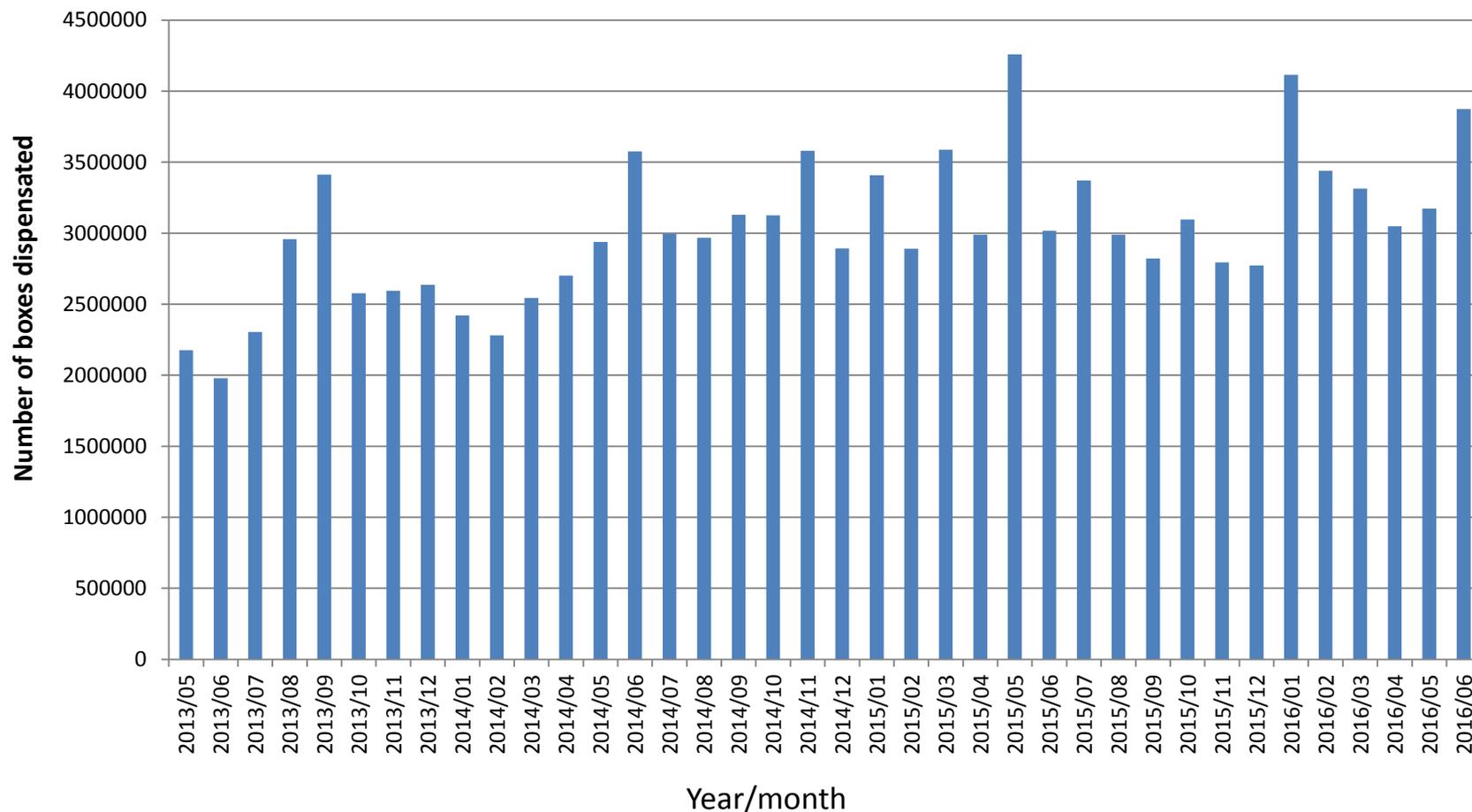
Drug Market Regulation

- Federal Law nº 10.742/2003: creats Drug Market Regulation Chamber – CMED

  ✓ Develops activities related to economic regulation of drugs market

  ✓ Stimulates the supply of drugs and the competitiveness of the sector

  ✓ Defines maximum price and readjustments

  ✓ Final decision by the council of ministers of CMED

Drug Market Regulation

- CMED Regulation nº 2/2015: Market Monitoring System of Medicines (SAMMED)

  - ✓ Drugs industries are required to register the units (packages) for medicinal products marketed in the country

  - ✓ Allows to estimate the overall consumption of drugs, including the antimicrobial medicines

Therapeutic classes of antimicrobials marketed in Brazil. 2010-2015.
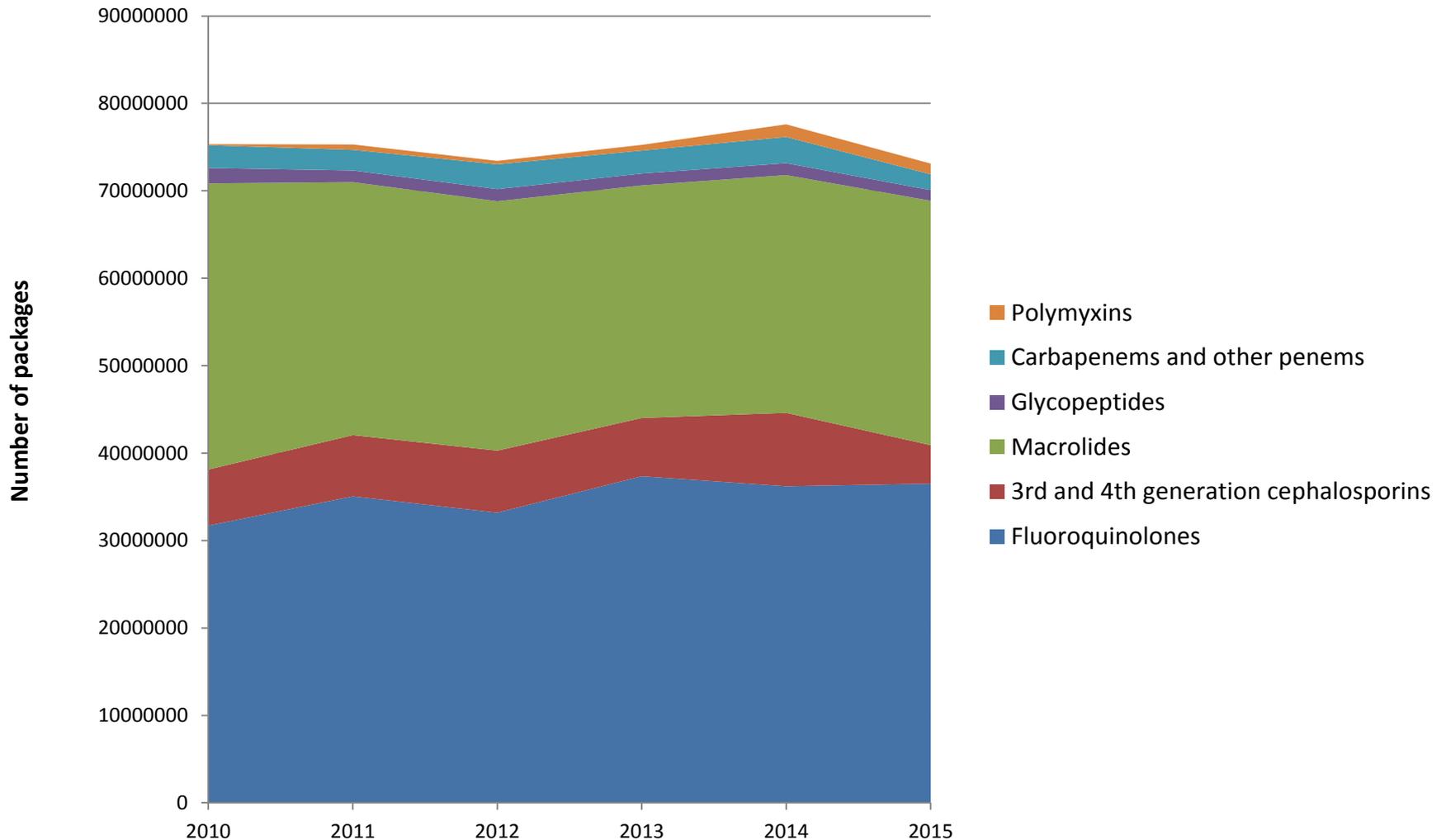
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Future Perspectives

- Develop studies and produce information regularly (reports)

- Integrate those data with information about resistance in microorganisms

- "Everybody should be engaged in efforts to preserve the effectiveness of antimicrobial medicines" (WHO, 2015)

> Effective communication strategies to improve awareness of the importance of rational use of antimicrobials to prolong the useful lifespan of these drugs

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Anvisa's Action Plan on Antimicrobial Resistance

- The Brazilian Health Regulatory Agency's effort to define the strategies that will integrate the national action plan

- Responsible for an action plan that covers regulatory issues related to medicines, food, health services, laboratories, and surveillance

- Examples:

  - ✓ Quality assurance of antimicrobial medicines (low concentrations of active ingredients)

  - ✓ Continuous integrated surveillance program to evaluate the antimicrobial resistance profile in food chains, including multidrug resistance

  - ✓ Network strengthening of analytical laboratories for antimicrobial resistance in health services

  - ✓ Improve healthcare-associated infection prevention and control

Obrigada! Thank you! Gracias!

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