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

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Context

• The burden of deaths from AMR can rise to 10 million 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 over-the-counter sales
  ✓ Optimize the use of antimicrobial medicines supported by appropriate and enforceable regulation
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
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
Expected results

• Reduce harmful self-medication

• Promote pharmacoepidemiology

• Highlight the need of professional indication for antimicrobial medicines consume
Total antimicrobials dispensation at drugstores and pharmacies enrolled at SNGPC. May/2013 to June/2016
Drug Market Regulation

• Federal Law nº 10.742/2003: creates 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.
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
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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