



**International Pharmaceutical Federation
Fédération Internationale Pharmaceutique**

PO Box 84200, 2508 AE The Hague, The Netherlands

FIP STATEMENT OF POLICY CONTROL OF ANTIMICROBIAL MEDICINES RESISTANCE (AMR)

Preamble

The FIP Statement of Policy on Control of Antimicrobial Medicines Resistance (AMR) was last revised in the year 2000. The problem of AMR has become more prevalent since then, and new concerns have been raised by scientific and health-care communities. Under these circumstances a number of prominent organizations, such as the WHO and the USA Centers for Disease Control and Prevention (CDC) have issued new recommendations. Therefore, the 2000 FIP Statement of Policy on Control of AMR has been revised to reflect current realities and make appropriate recommendations.

Background

Antimicrobial medicines resistance (AMR) is a major problem throughout the world and a growing threat to the global control of infectious diseases. It results in increased morbidity, mortality, and as a consequence the cost of health care.

With the introduction of penicillin in the 1940s, antimicrobial medicines began to play a major role in effectively controlling infectious diseases. However, soon after the introduction of antimicrobial medicines, it was recognised that some microbial pathogens developed resistance.

Initially, the problem of AMR was circumvented by the development of new classes of medicines as well as by the chemical modification of previously existing ones. Unfortunately, the development of new antimicrobial medicines cannot keep pace with the ability of microbes to develop resistance.

Since the early 1940s AMR has been observed in strains of *Escherichia coli* and *Staphylococcus aureus*. Since then, increased resistance has been observed in a variety of microorganisms such as *Streptococcus pneumoniae*. This and the more recently observed multiple-medicines resistance is threatening the control of infectious diseases globally. The problem of AMR is troublesome in both developed and developing countries. But in developing countries, the availability and appropriate use of antimicrobials are poorly controlled. This results in a higher incidence of resistance, particularly to the older antimicrobials.

The following are a few examples of the magnitude of the problem of AMR:

- Methicillin-resistant *S. aureus* (MRSA) is one of the most widespread causes of nosocomial infections worldwide. Recently, infection with novel community-acquired strains of MRSA (CA-MRSA) in previously healthy individuals without either direct or indirect association with health care facilities has emerged.
- Since the first report of a clinical isolate of *S. aureus* that demonstrated reduced susceptibility to vancomycin (vancomycin-intermediate *S. aureus* or VISA), clinical cases of infection with *S. aureus* isolates that are fully resistant to vancomycin (vancomycin-resistant *S. aureus* VRSA) have been reported.
- *Enterococci* are commonly recovered from patients with endocarditis and urinary tract infections. Since the first reported isolation of vancomycin-resistant *enterococci* (VRE) in 1987, VRE have been detected in hospitals and spread with an unanticipated rapidity.
- Fluoroquinolones have been widely used in the treatment of gonorrhea and pelvic inflammatory disease because of the efficacy and convenient dosing of this medicines class. However, as of April 2007, treatment guidelines from the Centers for Disease Control and Prevention no longer recommend use of these agents due to widespread resistance in *Neisseria gonorrhoeae* isolates.
- The spread of multidrug-resistant (MDR) and more recently, extensively drug-resistant (XDR) tuberculosis (TB) is a threat to advances in the treatment of TB and could even reverse recent gains. Due to the increased concern of co-infection of TB and HIV, XDR-TB could threaten the success of not only national TB control programs but also those of HIV/AIDS.
- Recognising that malarial medicines do not fall in the category of antimicrobial drugs, it is important to note that the progressive decline in chloroquine susceptibility has made this drug partially or completely ineffective in most malaria affected areas. Resistance is now emerging in *Plasmodium falciparum* to most classes of antimalarial drugs, with the exception of the artemisinin-based combination therapies.

Reducing the health, social and economic burdens due to the emergence of resistant pathogens is of paramount importance. However, effective reduction and control of AMR cannot be achieved by national initiatives alone. This will require a global strategy.

FIP supports the initiatives of the World Health Organization Global Strategy for Containment of AMR (WHO/CDS/CSR/DRS/2001.2), the US Centers for Disease Control and Prevention's (CDC) 12 steps to prevent AMR in healthcare settings (published November 2003), and the

eleven points of action directly related to human medicine and AMR in a strategy paper published by the Pharmaceutical Group of the European Union (Euro Surveill 2004; 9(1): 30-4).

Against this background, FIP undertakes to:

- Promote the establishment and/or strengthening of sustainable AMR and antimicrobial use surveillance systems.
- Promote cooperation among countries and professional organisations in the development and use of indicators to monitor antimicrobial prescribing practices.
- Encourage the development of policies and programs designed to increase the importance of AMR information for the market authorisation process.
- Support educational campaigns on the appropriate use of antimicrobial agents that are aimed at both the public and health-care professionals.
- Reinforce the principle that antimicrobial medicines for human and veterinary use be available by prescription or order of qualified health-care professionals only.
- Promote the discovery and development of new cost-effective antimicrobial agents.
- Encourage the discovery and development of alternative treatments and vaccines.
- Support the development of rapid and reliable diagnostic and susceptibility tests.
- Encourage the development of partnerships at an international level, in particular via existing international organisations, such as the World Health Organization (WHO).
- Promote the role of the pharmacist in the selection, procurement, distribution and use of antimicrobials.

The FIP urges governments and health authorities to:

- Design and implement a national antimicrobial surveillance plan and to develop and implement procedures for monitoring patterns of antimicrobial medicine use in human medicine, agriculture, veterinary medicine, and consumer products.
- Develop and implement measures for appropriate use of antimicrobials and prohibit the dispensing and sale or supply of these medicines without prescription or order of a qualified healthcare professional.
- Impose additional restrictions, when appropriate, on the prescribing of selected antimicrobial medicines to limit the risk of the development of resistance.
- Strengthen legislative and regulatory controls over authorisations to market, import, export, prescribe, dispense and otherwise supply antimicrobial medicines, as well as enhanced enforcement of statutes and regulations.
- Ensure that only authorised channels of distribution are used to minimise the availability of counterfeit and substandard medicines; thus assuring that the available antimicrobials meet the required standards of safety, quality and efficacy.
- Conduct health-education campaigns that promote the appropriate use of antimicrobials.
- Collaborate with health professional societies and associations to develop and facilitate the implementation of educational and behavioural interventions that will assist prescribers in appropriate antimicrobial prescribing.

- Collaborate in the establishment of infection control programs for effective management of AMR and ensure that all health-care facilities have access to such programs.
- Develop appropriate adult and child vaccination programmes for those diseases that are vaccine-preventable.
- Make available environmentally sound methods of disposal of antimicrobial medicines.
- Support the development of alternative means of animal husbandry to secure the discontinuation of the use of antimicrobials as growth promoters and in disease prophylaxis.

FIP urges pharmacists to:

- Give proper counselling advice and provide appropriate written information when dispensing antimicrobials.
- Encourage patients to take the full prescribed regimen and, if not possible, to appropriately dispose of any unused antimicrobial medicines.
- Work with prescribers to order sufficient doses to complete or continue a course of therapy.
- Recommend therapies other than antimicrobials for minor ailments.
- Provide updated medicine information on antimicrobials to prescribers as well as health-care professionals who administer or otherwise influence the use of medicines.
- Be actively involved in matters of hygiene and infections control in all health care settings.
- Effectively monitor the supply and use of antimicrobials by their patients.

This FIP Statement of Policy on Control of Antimicrobial Drug Resistance (AMR) replaces that which was adopted in 2000 in Vienna.

This Statement originated with the Board of Pharmaceutical Practice