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

## Preamble

The FIP Statement of Policy on the Control of Antimicrobial Resistance (AMR) was last revised in 2008. AMR has since been declared a global public health emergency necessitating the mobilisation of the whole of society to address this increasingly serious threat. AMR is recognised as a consequence of selection pressure developed through both rational and, in many cases, indiscriminate and unregulated use of antimicrobials in human, animal and environmental health. Adopting a “One Health” approach<sup>1</sup> should improve health and well-being through the reduction of risks and the mitigation of effects of AMR that originate at the interface between humans, animals and their various environments. Under these circumstances, the United Nations General Assembly (UNGA) endorsed a political declaration on AMR in September 2016 and a number of prominent organisations, such as the World Health Organization (WHO), the Food and Agriculture Organization (FAO), the World Organization for Animal Health (OIE), the Global Health Security Agenda (GHTA), the G7, G20 and G77 nations, and the Foreign Policy and Global Health Initiative group of nations have renewed commitments and issued recommendations. The 2017 FIP Statement of Policy on Control of AMR is thus a revision to reflect current issues and make appropriate recommendations.

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## Background

With the discovery of penicillin in 1928, antimicrobial medicines began to play a key role in effectively controlling infectious diseases. However, increasing numbers of microbial pathogens developed resistance soon after the introduction of antimicrobial medicines into clinical use. The problem of AMR was initially addressed by the development of new classes of antimicrobials and by the chemical modification of existing ones. The development of new antimicrobial medicines has, however, not kept pace with the ability of microbes to develop resistance.

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<sup>1</sup> The “One Health” approach recognises that the health of humans, animals and ecosystems are interconnected. It involves applying a coordinated, collaborative, multidisciplinary and cross-sectoral approach to address potential or existing risks that originate at the animal-human-ecosystems interface.



As a consequence, AMR is now a global public health challenge and an escalating threat to the control of infectious diseases worldwide. AMR results in prolonged illness, greater risk of infection spread, increased morbidity and higher mortality rates, with associated increases in both financial and societal costs. AMR is of concern in both developed and developing countries. AMR-related challenges are greater in developing countries as a result of factors such as limited human resources and regulatory, technical and infrastructural capacities. These include, but are not limited to, surveillance and monitoring of antimicrobial use and resistance, medicines distribution and use, medicines regulation and enforcement, and infection prevention and control. The nature and the extent of the AMR burden are not fully quantified. Additionally, antimicrobial medicines are among the most commonly reported substandard or falsified medicines.<sup>2</sup>

The World Health Assembly endorsed the Global Action Plan (GAP) on Antimicrobial Resistance in 2015 and with Resolution A69/24 Member States committed to developing national action plans by May 2017<sup>3</sup> with five strategic objectives, namely (1) education and awareness, (2) surveillance and research (3) infection prevention and control, (4) responsible use of antimicrobials, and (5) research and development. The overall goal of the GAP is to ensure, for as long as possible, continuity of the ability to treat and prevent infectious diseases with effective and safe antimicrobial medicines that are quality-assured, used in a responsible way, and accessible to all who need them. The United Nations General Assembly in its Political Declaration on AMR in September 2016 endorsed the GAP as a vehicle for countries to address AMR.

FIP unequivocally supports the UNGA Political Declaration on AMR, subscribes to the One Health approach and strongly endorses the World Health Organization's GAP on AMR as the blueprint to address AMR nationally and globally.

#### **AGAINST THIS BACKGROUND, FIP RECOMMENDS THAT:**

##### **Governments:**

- Demonstrate political will by mobilising relevant national ministries/departments to improve, collectively and collaboratively, the capacities of their national systems to address AMR in the One Health context.
- Develop, fund, implement, monitor and evaluate national action plans to contain AMR and formally involve all key stakeholders, including health care professionals, the private sector, academia, and civil society.

<sup>2</sup> WHO Factsheet. Substandard, spurious, falsely labelled, falsified and counterfeit (SSFFC) medical products. Available from: <http://www.who.int/mediacentre/factsheets/fs275/en/>

<sup>3</sup> [http://apps.who.int/gb/ebwha/pdf\\_files/WHA69/A69\\_24-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_24-en.pdf)



- Design and implement a robust, representative national surveillance programme, for monitoring and reporting patterns of antimicrobial medicine use and resistance in human, animal (livestock and companion) and environmental health.
- Ensure that all antibiotics listed in the WHO Essential Medicines Lists are available at all times. Develop a strategy for ensuring the sustainable production and registration of old antibiotics that may help address growing problems of medicine resistance and of other antibiotics that face serious shortage or stock outs. This may require designing approaches to facilitate their registration across countries, transferring technology to other manufacturers, or providing appropriate economic incentives to encourage their development and commercial availability.
- Measure the consumption of antimicrobials in humans and animals.<sup>4</sup>
- Develop and implement measures for the responsible use of antimicrobial medicines in human, animal and environmental health sectors, including the introduction of antimicrobial stewardship.
- Collaborate with health care professional and veterinary societies and associations to develop and facilitate the implementation of educational and behavioural interventions that will promote appropriate antimicrobial prescribing and raise awareness of AMR.
- Develop and encourage adoption of best practices guidelines and impose restrictions, when appropriate, on the prescribing, dispensing, compounding and use of antimicrobial medicines in all sectors to limit the development of AMR.
- Ensure that antibiotics are produced in pack sizes corresponding to their usual course length.
- Strengthen and enforce legislative and regulatory controls applicable to all sectors over authorisations to market, promote, import, export, prescribe, dispense, dispose and otherwise supply antimicrobial medicines including via the internet or telecommunications (telemedicine).
- Ensure that only authorised channels are used for the distribution of medicines. This will help minimise the availability of substandard or falsified medicines and ensure that the available antimicrobials meet the required standards of safety, quality and efficacy.
- Institute/Enforce regulations discouraging the dispensing and sale or supply of antimicrobial medicines without the prescription or order of a qualified health care or veterinary professional.
- Conduct health education campaigns that promote the responsible use of antimicrobial medicines to the public.

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<sup>4</sup> By measures such as daily-defined doses (DDD), the population correction unit (PCU), days of therapy (DOT), data related to pharmaco-epidemiology, import, procurement and/or tender;



- Establish infection prevention and control, hygiene and sanitation programmes for effective containment and management of infections and ensure that all communities and health care facilities have access to such programmes.
- Establish biosecurity and good animal husbandry practices for effective containment and management of infections in food animals and ensure that all farms and slaughterhouses have access to such programmes.
- Develop appropriate adult, child and (livestock and companion) animal immunisation programmes for diseases that are vaccine-preventable.
- Establish and enforce the adoption of effective antimicrobial medicines disposal and biosecurity practices to prevent the contamination of soil and water sources with antimicrobial medicines residues and antimicrobial resistant microorganisms, and ensure that all industries and farms have access to such programmes.
- Develop a “return and disposal” programme for unused or expired antimicrobial medicines and inform the public about the importance of using antimicrobial medicines correctly and, if unused, returning the medicines for proper disposal.
- Support the development of biosecurity and animal husbandry measures to encourage the discontinuation of the use of antimicrobial medicines as growth promoters and in disease prophylaxis and metaphylaxis.
- Include antimicrobial stewardship in pre- and post-professional education. Ensure availability and access to relevant education on antimicrobial use for all society.
- Support the discovery and development of new cost-effective antimicrobial medicines, alternatives to antimicrobials, and research into improved use of existing antimicrobials, including new combinations.

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#### **Pharmacists:**

- Work with governments to ensure adequate legislative control over the provision of antimicrobial medicines.
- Ensure that antimicrobial medicines for human use are supplied on the authority of a healthcare professional in accordance with country legislation and regulations.
- Ensure that antimicrobial medicines for animal use are supplied in accordance with country legislation and regulations.
- Actively discourage the inappropriate use of antimicrobial medicines.
- Acquire their antimicrobial medicines only from reliable sources in order to ensure their quality, safety and efficacy.
- Optimise antimicrobial therapy by advocating and actively participating in microbiology-informed antimicrobial therapy/diagnostic stewardship.
- Encourage use of diagnostic tools and evidence to inform empirical use.



- Ensure that the correct antimicrobial medicine is prescribed to the right person for the correct duration at the correct dose and dosing interval, opting for the narrowest spectrum agents where possible.
- Promote evidence-based medicine in that antimicrobial treatment is informed by infection-based, local antibiograms<sup>5</sup> from robust, representative antimicrobial resistance surveillance.
- Provide feedback to the patient on the responsible use of antimicrobial medicines and to the prescribers on the consumption of antimicrobial medicines and the impact thereof.
- Give proper counselling advice and provide appropriate written information when dispensing antimicrobial medicines.
- Monitor effectively the use of antimicrobials by patients and adherence to treatment.
- Encourage patients to take the prescribed regimen at the recommended intervals as directed by the prescriber.
- Recommend therapies other than antimicrobial medicines, including symptomatic treatment for viral and/or self-limiting conditions.
- Provide updated information on antimicrobial medicines to prescribers as well as health care and veterinary professionals, animal producers and other stakeholders in the food and agriculture sectors who administer or otherwise influence the use of antimicrobial medicines.
- Be actively involved in matters of hygiene, sanitation and infection prevention measures in communities and health care settings, respectively.
- Encourage immunisation generally and for influenza specifically, particularly in pre-winter months to help prevent upper respiratory tract infections.
- Implement health education campaigns focused on the importance of protecting effectiveness of antimicrobial medicines among prescribers, patients, veterinary and agriculture sectors.
- Actively discourage self-medication, use, or storage for future use, of leftover antimicrobial medicines by patients.
- Take responsibility for “return and disposal” programmes for the appropriate disposal of unused or expired antimicrobial medicines.
- Proactively inform medicine users about the proper disposal of unused antimicrobial medicines.
- Conduct and translate research on all facets of AMR, including but not limited to biomedical, clinical, socio-behavioural, policy, diagnostics and antimicrobial medicines discovery for the optimal management of infections in the context of AMR and antimicrobial stewardship in the One Health approach.

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<sup>5</sup> Antibiograms are tables showing how susceptible a series of organisms are to different antimicrobials



**AGAINST THIS BACKGROUND, FIP COMMITS TO:**

- Advocate the creation and increased awareness of national, regional and international electronic platforms that triangulate, in real time, trends in antimicrobial use and resistance within and between the human, animal and environmental health sectors in order to allow early warning of emerging resistance in any/all sectors to inform strategies for containment and to prevent transmission between and within sectors.
- Promote the establishment and/or strengthening of sustainable AMR and antimicrobial use surveillance systems in all health care settings.
- Promote cooperation among countries and professional organisations in the development and use of indicators to monitor responsible antimicrobial prescribing, dispensing, use and disposal practices.
- Facilitate and encourage the consideration of AMR information by regulatory agencies during the approval process for novel medicines.
- Develop and support educational campaigns on the responsible use of antimicrobial medicines aimed at the public.
- Develop and support educational campaigns on the responsible use of antimicrobial medicines aimed at those involved in food production as well as health care, veterinary and environmental health professionals
- Endorse the termination of use of critically important antimicrobial medicines in animals<sup>6</sup> for growth promotion purposes as well as the reduction of use for prophylaxis and metaphylaxis by advancing biosecurity and good animal husbandry practices instead.
- Promote the discovery and development of new cost-effective antimicrobial medicines by advocating for reform of reimbursement systems and novel incentive mechanisms that recognise the value of novel antibiotics and delink access and availability from return on investments and profit.
- Encourage the discovery and development of novel treatment modalities and vaccines.
- Support the development and uptake of rapid and reliable diagnostic and susceptibility tests.
- Promote the role of the pharmacist in the sustainable production of, access to and the responsible use of antimicrobial medicines, including selection, procurement, distribution, compounding, use and disposal.
- Promote responsible production of antimicrobial substances and antimicrobial medicines, including waste disposal and waste water handling, and encourage the selection and procurement of medicines produced in an environmentally acceptable way in tenders/reimbursement systems.

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<sup>6</sup> World Health Organization (WHO). Critically important antimicrobials for human medicine. 3rd revision. 2012. ISBN: 9789241504485. Accessible from: <http://www.who.int/foodsafety/publications/antimicrobials-third/en/>



- Reinforce the principle that antimicrobial medicines for human use are only supplied on the authority of a healthcare professional, and that antimicrobial medicines for either human or animal use are only supplied in accordance with country legislation and regulations.

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| This Statement can be quoted as:                                      | : | International Pharmaceutical Federation. FIP Statement of Policy - control of antimicrobial resistance (AMR). The Hague: FIP, 2017. Available at: <a href="http://www.fip.org/statements">www.fip.org/statements</a>   |
| This Statement references the following FIP Statements and documents: | : | International Pharmaceutical Federation. Fighting antimicrobial resistance: The contribution of pharmacists. The Hague: FIP, 2015. Available at: <a href="http://www.fip.org/files/fip/publications/2015-11-Fighting-antimicrobial-resistance.pdf">http://www.fip.org/files/fip/publications/2015-11-Fighting-antimicrobial-resistance.pdf</a> |

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